IN THE UNITED STATES DISTRICT COURT FOR THE

SOUTHERN DISTRICT OF WEST VIRGINIA, HUNTINGTON DIVISION

BEFORE THE HONORABLE ROBERT C. CHAMBERS, JUDGE

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CLAUDE R. KNIGHT and CLAUDIA STEVENS, individually and as personal representatives of the Estate of BETTY ERLENE KNIGHT, deceased,

Plaintiffs,

vs. No. 3:15-CV-06424

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Volume 6
Pages 960 through 1100

Defendant.
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REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL

THURSDAY, OCTOBER 11, 2018, 1:00 P.M.

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For the Plaintiffs: CHILDERS, SCHLUETER & SMITH
1932 North Druid Hills Road, Ste 100
Atlanta, Georgia 30319
BY: C. ANDREW CHILDERS
and EMILY TWEED ACOSTA

URY & MOSKOW
883 Black Rock Turnpike
Fairfield, Connecticut 06825
BY: NEAL L. MOSKOW

(Appearances continued next page...)

Reported by: KATHY L. SWINHART, CSR
LISA A. COOK, RPR-RMR-CRR-FCRR
Official Court Reporters
(304) 528-2244

Proceedings reported by mechanical stenography, transcript produced by computer-aided transcription.

APPEARANCES (Continued)

For the Plaintiffs:

FERRER, POIROT & WANSBROUGH
2100 RiverEdge Parkway, Suite 1025
Atlanta, Georgia 30328
BY: HUNTER VANCE LINVILLE

For the Defendant:

TUCKER ELLIS
925 Euclid Avenue, Suite 1150
Cleveland, Ohio 44115
BY: JOHN Q. LEWIS

COVINGTON & BURLING
One City Center
850 Tenth Street NW
Washington, D.C. 20001
BY: PHYLLIS ALENE JONES
and NICHOLAS HAILEY
and JESSICA PEREZ

JACKSON KELLY
Post Office Box 553
Charleston, West Virginia 25322
BY: GRETCHEN M. CALLAS

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HUNTINGTON, WEST VIRGINIA

THURSDAY, OCTOBER 11, 2018, 1:04 P.M.

(Jury not present)

THE COURT: Good afternoon. Are we ready to proceed?

MR. LEWIS: Yes, Your Honor.

THE COURT: All right. Let's start first with the defendant's pre-emption motion, with your argument first.

MR. LEWIS: Thank you, Your Honor. Give me a second to get set up.

THE COURT: Sure.

(Pause)

MR. LEWIS: May it please the Court, thank you, Your Honor, for the opportunity to be heard on our motion for directed verdict.

We're moving for directed verdict on all of the claims left in this case on the grounds of pre-emption. And I guess I want to first start with -- I had an opportunity to review the plaintiffs' filing from this morning and I've got to be honest. I was a little bit shocked by one of the things, among others, that was said in that paper. And it's, and it's this in particular:

"At the outset, it is important to note what plaintiffs are not claiming. Plaintiffs are not making a claim that the Medication Guide is defective."

That's right in the plaintiffs' papers. I think that's a very disingenuous statement to the Court. The plaintiffs have tried this case on the Medication Guide every single day, including from the opening statement. In fact, from the opening statement that Mr. Childers made, "And, so, --"

MR. MOSKOW: Your Honor, my understanding from the, before evidence started in this case is that we were not to rely on the unofficial transcripts. And, yet, you know, that's how the argument is starting. I'm a little concerned that we have not had access to an official transcript for purposes of this type of argument.

MR. LEWIS: May I respond to that?

THE COURT: Yes.

MR. LEWIS: Two things. One, these are actually official transcripts. We confirmed that with our court reporters that these are official transcripts.

And, number two, I'm quite clear that we discussed about the transcripts, that they could be used for things like this, for court proceedings and things along those lines. And we were going to table perhaps whether the jury could see them because of some other issues, but clearly relevant for this purpose and this is what he said.

THE COURT: Well, the Court recalls that we did discuss the fact that one side was getting daily transcripts. I certainly made clear that we would explain

to the jury that there wouldn't be transcripts available for them.

I don't know or recall specifically understanding that either side intended to use them for argument of motions in the case. Frankly, I haven't had a chance to talk to either of the court reporters to determine whether they perceive these to be official transcripts or not. I haven't looked to determine whether they've been docketed.

Do you know?

MR. LEWIS: Yes.

THE COURT: Well, if they've been docketed, then I suspect the certification is attached from the court reporter that they are official transcripts.

MR. LEWIS: It is. Yeah, they're -- this is what we're getting: "We," the court reporters, our great court reporters, "certify --" and that's on the record right now, "certify that the foregoing is a correct transcript." This is an official transcript.

MR. MOSKOW: Your Honor, they were made official this morning after we had -- or at the same time we were filing our brief I've just been informed.

So, regardless, we also have a concern about, you know, reference to opening statements which are clearly not evidence for purposes of the directed verdict.

So we're just, we're just concerned that we're not

playing, you know, with the same pieces on the table and want to make sure that everybody has that same opportunity.

THE COURT: Well, I'm going to allow the defense to continue. I certainly think that they are allowed to use counsel's statements to explain their view of what counsel and the plaintiffs' position is with respect to legal issues certainly. So I'll allow them to continue.

MR. LEWIS: Thank you, Your Honor.

Mr. Childers said in opening statement, and there's no question about it, we all were here, "We're going to show you with this Medication Guide there are several pieces of information missing that the patient should have known."

And we wrote these things down and we've been referring to them throughout the whole trial. So with the four and a half days of testimony, repeatedly this has been trotted out and repeatedly even ending with Dr. Ashhab and the plaintiffs, "Did you know about this? Did you know about that? Should that have been in the Medication Guide?" Over and over and over these five things.

So I was pretty shocked to see that the response paper to our pre-emption motion was, "We're not criticizing the Medication Guide." But I know why they did that. They did that because if they are trying to challenge the Medication Guide, these claims are pre-empted and there's no question about it. It's right in the federal regulations.

We cannot change the Medication Guide without FDA approval. There are no exceptions to that. There's no voluntary change in the Medication Guide. And if their claim is premised on the Medication Guide and the challenge to it, the claim's pre-empted, clear as day. So that's why they're making the argument.

But putting aside that piece, the claim is not saved by what they say in their papers. So what they say in their papers is, "We're not challenging the Medication Guide but we're saying you should have said other stuff to the plaintiff or to the doctors or whatever."

But as we heard from Dr. Plunkett and even the BI witness, Michelle Kliewer, and, and the law says this, everything is a labeling. So any communication about the product, whether it's a Medication Guide, a physician label or something else, every communication about the product is a labeling. It's a label.

So the real question in this case is, does what the plaintiffs are saying we should be doing under West Virginia tort law, will that require us to do something we can't do under federal law, basic conflict pre-emption? If we can't make both masters happy, then that's conflict pre-emption. Federal pre-emption always wins out.

So that's our argument here, that it doesn't matter if really -- they're clearly challenging the Medication Guide.

If you told that jury that, "Oh, by the way, they're actually not challenging it," we'd have the most confused jury in West Virginia history. But it doesn't really matter for purposes of this analysis because whatever they're saying is basically they're trying to impose a duty under West Virginia tort law. And the question is, does that make us violate federal law.

And, so, Your Honor, if you don't mind, I have this -- to keep it in my head how this conflict pre-emption analysis works, I have a little flowchart I'd like to put up.

THE COURT: Go ahead.

MR. LEWIS: So this is -- this basically helps me understand the case law and how it all works together.

I think the best case to look at, frankly, is a case that involves a drug right in this class of drugs. It's the *Utts* case that's from recently this year out of New York and it's about Eliquis which is a novel anticoagulant medication, the Eliquis case. It goes through this analysis pretty well. There's some other cases we cited as well. But this is basically the analysis.

If you have a label and it's an FDA approved label, the first question is, can you change that without FDA approval. Because if you can't change it without FDA approval, then any challenge to that is pre-empted.

And that's what this -- this is kind of the first

level. That's where the Medication Guide comes in. And that's where the communication to the patients comes in. And pretty much any challenge at all is not permitted without FDA approval. But there are some exceptions to that.

So the exception to that is for brand manufacturers, there are certain exceptions where they can voluntarily change the label. Typically, that's called Changes Being Effected section. And what that allows brand manufacturers to do if they acquire new information that supports a change, let's say there's new information that's discovered the FDA hadn't considered before, then did that newly acquired information support a change under the CBE, or the Changes Being Effected section.

What the case law makes clear, and *Utts* describes this very, very well, the plaintiff has to demonstrate that there was newly acquired information. You can't just say, "Oh, you could have changed the label under CBE." The plaintiff has to say, "You should have changed the label because you had newly acquired information."

THE COURT: Doesn't newly acquired information include analysis?

MR. LEWIS: Well, if the FDA had the material -- and there could be a, there could be an argument here about whether that's the case or not, but if the FDA had the

material already and the analysis was done, then that, that is not newly acquired information. But under *Mensing* --

THE COURT: But you just said "and the analysis is done."

MR. LEWIS: Correct.

THE COURT: And it seems to me throughout plaintiffs' evidence about the process here by which you got, you got approval for Pradaxa and then changed the label over time was based upon new analyses of the RE-LY study and internal reports.

And you know much better than I do how often through plaintiffs' evidence there were key people from Reilly to Connolly to these different BI employees where they all talked about do we need to start explaining something different about some of these risks. And there were a number of different facets to that.

But why isn't all of that new analysis of existing data?

MR. LEWIS: It could be. It could be. But look at what the challenge is here in this case; never tested in severe renal patients. There was no new analysis. That was known and analyzed by the FDA before the drug was approved. And there was no new information submitted by the plaintiff to change that.

THE COURT: But weren't there reports from --

exchanged in some of these emails and then in some of the literature where there was further analysis of patients who had severe renal problems and how this drug might have a different result with them that ultimately rose to the point where you even included a contraindication for severely impaired renal patients who were taking other drugs?

MR. LEWIS: No. That was done at the beginning, Your Honor.

THE COURT: At what point -- wasn't the label changed at one point to say it's contraindicated to give Pradaxa to these patients?

MR. LEWIS: No. At the beginning, the evidence is from Michelle Kliewer that the evidence was the company before the drug was approved submitted a label that said it should be contraindicated in patients with severe renal function between 15 and 30 --

THE COURT: Okay.

MR. LEWIS: -- CiCL or CrCL. That was submitted to the FDA prior to new drug approval.

The FDA struck that out, that contraindication out and instead said, no, we want you to make a 75-milligram dose for those patients between 15 and 30. That was all done before approval.

THE COURT: That was done. What I'm referring to -- and maybe I just misunderstand the sequence.

Plaintiff quotes from it, so that's what refreshed my recollection that the evidence was there. But on Page 3 of plaintiffs' response they say, "Among information added to the physician label after product launch is the following." Number 2, that P-gp inhibitors in patients with severe renal impairment Pradaxa use not recommended.

MR. LEWIS: Oh, the P-gp inhibitor piece, yeah. I'm sorry. I was thinking of the contraindication at all for use of the product at all.

THE COURT: Right.

MR. LEWIS: Okay. That's what they're saying in Number 1 there.

THE COURT: Okay.

MR. LEWIS: Number 1 is pre-empted. Never tested in patients, the FDA knew that, yeah.

THE COURT: All right.

MR. LEWIS: Number 2, never tested 75 milligrams. That's pre-empted. They already knew that and there was no further analysis done.

Now, don't take Pradaxa and Coreg. There was a label change between the time that the drug was on the market and later in April of 2013.

THE COURT: And that's what I was referring to.

MR. LEWIS: Okay. So that's what Your Honor was referring to. There was a label change on P-gp inhibitors.

But that label change was made in April of 2013 before the prescription that led to the injury by Mrs., that Mrs. Knight complained of or her children now complain of.

The label was updated before the prescription that caused the complication. That's why we were focused so much on the April, '13 change because Dr. MacFarland is out of the picture at that point in time. She's not prescribing Pradaxa anymore.

Mrs. Knight goes in for a stent procedure in April of 2013. And Dr. Stephanie Graham who for the first time in May prescribes -- right after that stent procedure prescribes her Pradaxa.

And at that time, that label is updated to include the contraindication on P-gp inhibitors. The doctor chose to prescribe it anyway -- actually, it wasn't a contraindication. It was a "not recommended" which is a big difference. I apologize for the misstatement. It was a "not recommended" and the doctor chose to prescribe it anyway in the face of that "not recommendation."

So -- and there was certainly no new information between April and May of 2013. So that claim is pre-empted because it was already in the label.

The no reversal agent, that was known by the FDA at the time that the product came onto the market in 2010. That's pre-empted and there was no new information about that

piece.

More likely to have a GI bleed. That was right in the label of the physician label at the time of the new drug approval.

So every single one of these, every single one of these was either in the label at the time or certainly in the label at the time that Mrs. Knight received the Pradaxa prescription.

So the P-gp -- I'm getting my -- right. So let me get my facts straight on this.

So the update on the P-gp not recommended was done in November of 2011, about a month after the -- Mrs. Knight started taking Pradaxa and certainly well before the decision was made to prescribe her Pradaxa in 2013 that led to the injury.

So all five of those claims ought to be pre-empted.

And whether we're talking Medication Guide or we're talking physician label, the same analysis is true. In the first instance can we make a proposed change without FDA approval, any challenge to the Medication Guide or direct patient communication, there's no evidence in the record at all and the regulations don't provide for us to be able to change the communication.

And, by the way, that makes complete sense. The FDA doesn't want us to submit a Medication Guide on the one hand

and then sneak in other communications in other forms on the other. When the FDA has an approved Medication Guide, that's the communication to the patient. And the manufacturer isn't permitted.

I mean, this rule runs both ways. Right? It runs against plaintiff lawyers here, but it also runs against us. We're not allowed to submit different types of information to patients that contra -- is contra to the Medication Guide. So that, that takes care of all patient communications in the first instance.

In the second instance, there's no newly acquired information that supports a different label at the time that the label existed for the prescription where she took the Pradaxa that eventually led to her injury.

We don't even get in this case to a clear evidence analysis. And I know that's the third step in the process. But really none of the claims here get to clear evidence because usually if a plaintiff comes forward with newly acquired information, you should have gone through the CBE route, you should have changed your label, typically a manufacturer will come forward and say, "Well, wait a minute. The FDA would have rejected that change."

THE COURT: How does the label -- what was the process for the label changes that did occur?

MR. LEWIS: The process for the --

THE COURT: For the label changes that did occur over time after the new drug approval.

MR. LEWIS: It depends on which one specifically. But typically there would be a submission to the FDA to support a label change. There's like a supplement or submission that you ask for FDA approval. And then, and then the FDA decides whether or not to approve it.

THE COURT: Well, as I understand it, some of plaintiffs' criticism and basis for failure to warn is based on the premise that at different points in time you have given stronger warnings in the label, but that they are -- you've had that information and should have known all along that this should be included.

And the evidence is that even with respect to these issues, there have been iterations of the label. There have been changes in the label.

MR. LEWIS: Sure.

THE COURT: And were those changes the result of CBE proceedings with the FDA in each instance?

MR. LEWIS: I'm not sure if it's in each instance, but in most instances --

THE COURT: Okay.

MR. LEWIS: -- it's either that or a communication directly with the FDA that, where we ask for -- we didn't make the label change before the FDA approval. We may have

made the label change, submitted it, and then the FDA approved it. It just depends.

THE COURT: You know, it probably won't be a surprise to you that this is fairly confusing to the Court. I spent a fair amount of time this morning first just reading through the *Dolin* case, the Seventh Circuit case.

MR. LEWIS: Right.

THE COURT: And I actually had been reading that before I even got plaintiffs' response. So I admit that -- and I'll ask them about this. I was surprised a bit about the plaintiffs' characterization of their criticisms of the Medication Guide. You've already raised that.

But as I walked through that *Dolin* case where they did find pre-emption, it was, there was a lengthy discussion where at many different turns in the FDA process over time the manufacturer had tried to get changes in the label and had been denied, refused.

And at the end of the day, the very warning that the plaintiffs advocated in *Dolin* was pretty much what the manufacturer had sought, more or less, to get the FDA to allow and had been refused.

I don't see that sort of fact pattern here at all where it seems that the -- you've gotten subsequent changes in the label that plaintiff has pointed to as evidence that you folks knew or should have known that these were warnings

that were necessary and appropriate.

So these, these weren't warnings that were, where you tried to warn and the FDA said, "No, you can't do that." Clearly under *Dolin* that was the reason that the Court determined that those were pre-empted.

But here we don't have that sort of pattern where -- I guess what it comes down to is where you've shown that you couldn't do what plaintiff asked because the FDA had rejected those positions other than I guess maybe the argument on the 75. But --

MR. LEWIS: Well, no. So let me, let me clarify it.

THE COURT: Go ahead.

MR. LEWIS: It depends on what the claim is.

THE COURT: Right.

MR. LEWIS: Right. So it's all about what challenge are you trying to make. The plaintiff has to make some sort of challenge. They just can't throw everything against the wall and say, "I generally think your label -- what about the label is wrong?" They've picked their five things about the communication that are wrong. And when we tick through each one of those, we see that each one fails independently for different reasons.

So, yes, there were label changes that were made over time, perhaps due to newly acquired information, that may

have been in completely different areas that aren't at issue in this case.

What's at issue in this case are those five things. That's what they're saying we did wrong with our labeling. And when we look at all five of those things, we see that they all -- never tested in severe renal patients. That's something that the FDA knew at the time that it approved the drug and that is not a challenge that the plaintiffs can make in this case. They knew that already.

And there's been no newly acquired information. We don't even get to clear evidence because the FDA already knew and there's no newly acquired information.

In *Dolin* what had happened was we had a situation where there was newly acquired information by the company with respect to particular challenges to the label. And therefore, the defendant came forward and said, "No, wait, the FDA has actually specifically rejected those changes."

But that's why this flowchart is helpful because we don't even get to that analysis if in the first instance there was newly acquired information or the FDA already knew about the information.

And when we tick through those five, never tested the 75-milligram, again that is already known by the FDA at the time, every single one of those.

THE COURT: What about the characterization of

these internal emails and discussions about some of the studies as newly acquired analysis, new analysis of already acquired information that the, even the BI people recognized could suggest that there should be a way of testing for plasma concentration levels and some of those other things?

MR. LEWIS: All right. Well, let me, let me put that one aside for just a second --

THE COURT: Okay.

MR. LEWIS: -- because that's not on this list. That hasn't been part of their challenge to the communications that we made to the patient or the physician. There's no, there's no monitoring --

THE COURT: Well, he didn't write it on this chart but then he made -- elicited testimony about it through a number of witnesses.

MR. LEWIS: But their, their argument all along has been exactly, has been exactly this, these, these criticisms. And for any of these criticisms, there have been, there's been no evidence of new analysis on these issues, none, that the FDA didn't already know about.

And on the monitoring, remember that there was a, there was a change that was -- or a suggestion that was struck out -- even on the monitoring there was a change that was struck out pre-approval that suggested that the aPTT levels over 80, you know, could be used as a guide for physicians.

But the important thing is that the expert, Dr. Plunkett, did not testify, and even Dr. Ashhab did not testify that the label was defective or deficient or anything that the company said was defective or deficient because it didn't have something in there about monitoring. That hasn't been the testimony.

They've run through this list with every single witness. They've talked about monitoring. They've certainly suggested here and there that maybe you should monitor and you don't really have a monitoring --

THE COURT: I thought it was pretty explicit from some of their experts that they testified that BI should have developed and informed physicians of the need and method by which to monitor blood plasma levels with Pradaxa.

MR. LEWIS: To my knowledge, that has not been a criticism of the label. They haven't put that list out. It's not on there. I mean, they've asked the plaintiffs the questions. They did not cover monitoring with the plaintiffs.

THE COURT: How is that not implicating the label when they complain -- when the experts testify that BI failed to inform physicians of the need and method to monitor blood plasma levels? How is that not a label deficiency? That's how you communicate to the doctor.

MR. LEWIS: Well, they haven't presented that as a

criticism of the label. They've been challenging it on these other grounds. And at a minimum, these all have to be out.

Let's just say for the sake of argument that the Court finds that, you know what, I think the monitoring piece, that piece is a challenge that, you know, maybe there was newly acquired information and I don't find clear evidence --

THE COURT: Let me stop you there --

MR. LEWIS: Okay.

THE COURT: -- because as I think -- it seems to me that's what I've always considered to be part and parcel of criticism number one, never tested on severely impaired renal patients.

And as a result, the company didn't know, didn't develop and then report to doctors the means and method to do monitoring. And subsequent to Pradaxa being approved, they had internal discussion about the desirability, and from some points of view the necessity, of being able to develop that.

So I don't see how that's not inherently a criticism of the label.

MR. LEWIS: Not in that respect. That, that -- never tested in -- every time that they talked about bullet number one on their criticism, they've always said -- and it

was clear when they talked to the plaintiffs. "Would you have used this if you knew that it wasn't tested in severe --" their complaint has always been we didn't do a clinical trial on those patients. They've never tied monitoring to that claim in this case.

THE COURT: Well, I mean, I don't get that because their criticism isn't simply never tested on severe renal impaired patients. It is that because you never tested it on these patients, you did not know and should have known that for severely impaired renal patients there ought to be a way of testing and monitoring their plasma levels so that as -- if they get too much Pradaxa in their system because of that poor renal function, they've increased their risk of bleed without improving their risk of avoiding stroke.

So, I mean, I appreciate that you're using his argument and that these are the points he made. But I don't -- I guess I don't see how in this first instance it's not a criticism of the label because it is a criticism of the label if the label is where BI should tell doctors whether and how to monitor blood plasma levels.

MR. LEWIS: But that's not the bullet number one that they've been arguing the whole trial. As I say, those five should be out because they have argued that the deficiency in the communication is that we didn't tell people that it wasn't tested.

The monitoring issue, to the extent the Court's going to allow the plaintiffs to pursue that failure to warn theory that in my view they haven't presented throughout the trial but, you know, we just maybe agree to disagree, but these five things are all out.

I mean, that first bullet is -- says nothing about monitoring. And when they talk about that bullet, they've never tied that to monitoring in any way.

They've always tied it to you didn't test it at all. You didn't do a clinical study or trial or you didn't even put this in patients at all before you brought it onto the market, severe renally impaired. You excluded them from the clinical trial. How many times have we heard it? You purposefully excluded them from the clinical trial.

THE COURT: Okay. So if I agree with you that they are not permitted to argue that the label is defective for its failure to report that there was no testing of severely impaired renal patients, they nonetheless may be able to argue that the label is deficient because it did not include a means or method for checking blood plasma levels in these patients.

And they had newly acquired information through the form of new analyses that they discussed in their emails and elsewhere about the appropriateness of undertaking that step in issuing a label consistent with that.

MR. LEWIS: Okay. So may I break that down a little bit?

THE COURT: Sure.

MR. LEWIS: So let's carve that, how Your Honor described that piece.

THE COURT: Okay.

MR. LEWIS: Let's just put that aside --

THE COURT: All right.

MR. LEWIS: -- for just a second.

So there are two sort of discussion points.

Number one is any criticism of the patient communication is out on pre-emption. We cannot change the Medication Guide and there's no way to communicate directly with the patient in any other way without prior FDA approval.

So the first thing is they can't even argue the monitoring opinion is a direct to patient violation or deficiency. They cannot argue that. Any claim is pre-empted if it relates to the company's communication with the plaintiff. So that's out. I mean, that's just -- that's in the FDA regulations.

But if the Court permits the plaintiffs to make an argument that -- and, again, I don't think they've made this argument. Dr. Plunkett testified that the physician label was irrelevant. They have not presented their case this

way.

But if they are suddenly going to be able to argue, well, now the physician label is relevant and the deficiency in the physician label is the fact that you didn't tell physicians that you need to monitor the patients because there was newly acquired analysis done in the paper or the RE-LY, the Reilly paper and you should have made a change or something along those lines to give doctors more information, I still think that claim fails for other reasons, but it may not be pre-empted.

It may fail for causation or the fact that it's not even within the scope of the duty in West Virginia, but it may be able -- it may be able to survive pre-emption. I mean, I think there are arguments against it, but let's just put that aside.

But all of these are out. And the Medication Guide and any challenges to what we said to patients has to be out under pre-emption principles. And the only thing that's possibly left is -- that survives pre-emption analysis perhaps is the monitoring piece which may fail for other reasons that we may talk about later when we talk about the kind of round two of our directed verdict.

But these and the direct communications to the patients have to be out on pre-emption. We don't even get to clear evidence. Like in *Dolin* they had to get to clear evidence

because there was no information on any of these things, any of these.

THE COURT: Okay. Thank you.

MR. LEWIS: Thank you.

MR. MOSKOW: May it please the Court, thank you for the opportunity to brief this overnight. And while I understand some of the language may have been not as artful as it could have been, I think I can give the Court a, kind of a big picture of where we are.

THE COURT: All right.

MR. MOSKOW: And then I'd love to hear or answer some of the Court's questions that I just heard during Mr. Lewis's argument.

One of the -- let me just start by saying we think that this motion has already been decided as part of the summary judgment briefing and we quoted that in the papers. We think it's untimely. There was a scheduling order for dispositive motions and this was not brought. We think it can be ruled on that. But we do want to address the merits and so let me kind of jump right in.

And at its most basic, Your Honor, this is about changes that were actually made to the label that were never communicated to Mrs. Knight and her family. And while I appreciate Mr. Lewis's reliance on the five items there, I think the record is clear these are five items that were not

communicated to the Knight family. And that's the gravamen of, of these items.

But both Dr. Ashhab and Dr. Plunkett spoke at length about the need for physicians to have additional information specifically with regard to whether or not there is a therapeutic range, whether or not there's a value not to be exceeded, and whether there's an ability to identify patients who are at particular risk, the one in five that we've heard about repeatedly in this case.

So those matters while not on this particular list were certainly articulated in front of the jury.

THE COURT: And those are part of a failure to warn because the label didn't address it.

MR. MOSKOW: That's correct, Your Honor.

And I, I want to highlight for the Court -- and I don't have the benefit of the daily transcripts. But I want to highlight to the Court's memory the deposition play of Michelle Kliewer who specifically stated that there was analysis, internal analysis with regard to this therapeutic range and this idea of a cutoff value of 215 nanograms per milliliter or 200 nanograms per milliliter which was never communicated to the FDA.

So whether the launch label included information or didn't include information goes right to the heart of plaintiffs' claims. And I think that may be a good place

for me to, to transition, Your Honor.

If we were to look at Exhibit 5881, which is the defense version of the launch label -- I'm going to put it up on the screen, Your Honor.

So this is the highlight section in the launch label, Your Honor. And just to superimpose on top of it, the highlight section in the January, 2012, label which is Plaintiffs' Exhibit -- oh, let me start.

If you note, Your Honor, this section in particular there is no mention of drug interactions. And there's no -- well, that's the part I really want to focus on right now. I'm going to switch gears a little bit.

And then over here there's no specific information about assessing renal function.

And when we superimpose Exhibit 88, the January, 2012, label, you'll see now there's an addition of the P-gp inhibitors in patients with severe renal impairment, Pradaxa use not recommended.

And you'll also see that there is information here about assessing renal function during therapy and adjusting the therapy accordingly.

These were changes that were actually initiated without FDA approval through the CBE process in November of 2011. And then there was a negotiation. Once the label was changed unilaterally, there was a negotiation between

Boehringer and the FDA. And this January, 2012, label is the product of those negotiations.

There is not one scintilla of evidence in the record that the defendants sought to include in the Medication Guide this information at the time they made the unilateral change.

In other words, when they made the unilateral change and then there was a negotiation with the FDA, there is not any evidence in the record in this case that during that period of negotiation they sought to include the same information in the Medication Guide.

We would submit that the defendant cannot meet its burden on impossibility pre-emption without showing that they requested the change and that it was not made. We're not saying that they could make it unilaterally in this case. But we're saying once they unilaterally put the information into the label, they had an obligation to inform patients in West Virginia.

And the only evidence that we have of their attempts to inform patients in West Virginia of the risks and benefits of Pradaxa are a TV commercial which is not subject to the FDA pre-approval. It's a whole different regulatory scheme. They could communicate with patients directly by TV. There's no indication that they ever tried to communicate directly by TV that patients should not take Coreg and

Pradaxa at the same time. So that's, that's the one hand.

The other hand, Judge, is that if this is the only information that they've conveyed to, to patients in West Virginia -- when I say "this," I mean the Medication Guide -- then the only evidence in the record is that they failed to warn on these things.

So -- and I'm pointing at the board that we've been talking about with the five things. So they can't have it both ways. The defendants can't say they're meeting their, their obligation under West Virginia law to warn of known hazards of the drug when they are specifically identifying them to physicians but not communicating them to individual patients.

And that gets me right to the, the nub of the point where Mr. Lewis started his argument and the Court's question about our language in our briefing.

The plaintiffs' position is that the Medication Guide is as much evidence of what was not done as it is evidence of what was done. In other words, by pointing out that information is not in the Medication Guide, we are establishing that Boehringer never met its state law obligation to specifically warn patients of the risks associated with Pradaxa.

I think this is particularly significant here, Judge, when I know we've used language like guinea pig and it's

evocative language and I'm sure, you know, that there's a, a sense that that's not fair.

I want to point out to the Court, though, if we look at the launch label again -- this is 5881 -- if we go to the section on clinical trials -- I'm sorry. It's Section 12.3 Your Honor, "Pharmacodynamics." And specifically it relates to severe -- I'm talking about the area at renal impairment that's on Page 5815. And you'll see -- and I'm going to really hone in on this.

You'll see that they include Table 3 which identifies normal, mild, and moderate renal impairment. And you see how it's highlighted underneath that, Judge. That's because in Exhibit 88 in Section 12.3 on Page 6 the defendants have now added -- excuse me -- defendant has now added not only severe renal impairment, but you'll see they've added a statement underneath, "Patients with severe renal impairment were not studied in RE-LY. Dosing recommendations in subjects with severe renal impairment are based on pharmacodynamic models."

MR. LEWIS: I'm sorry. What date is that label?

MR. MOSKOW: Page 6 of 88.

MR. LEWIS: What's the date, though?

MR. MOSKOW: This is January, 2012.

Your Honor, so Boehringer updated its physician's label after the FDA approved the launch label which had no

information about severe renal, had no information that the patients had not been studied.

So there was an update to the label that specifically references that, but it's not communicated to individual patients either in the Medication Guide, on TV, in a direct mailing, in a "dear patient" letter. Dr. Plunkett talked about the ability to do that.

And we want to make clear, Your Honor, that drug companies are permitted to communicate info in the label direct to consumers. That's why we have these TV commercials.

And the statutory scheme or the regulatory scheme for that is that they submit the commercials to the FDA, but they don't have to wait for FDA approval to play the commercial.

Now, they do so at their peril. They may be subject to a cease and desist letter if it's inaccurate. But if it's consistent with what's in the label, they're allowed to communicate that directly to consumers.

There's no indication in this case that at any time after Mrs. Knight started on this drug that a commercial was played in Connecticut that communicated the things that they were already telling to doctors, let alone the things that we say they should have told doctors but have not.

The, the reliance on a, on a specific regulation which

has never been interpreted by any court at this late hour to try to knock out all of these claims to me really reflects the fact that there is no legal basis to do so. It would have been challenged in summary judgment. We would have seen an affidavit from a regulatory affairs expert on their side saying all of these things.

And the, the suggestion that these are new arguments, that they couldn't anticipate them, is belied by the fact that in the very briefing for summary judgment, the plaintiff specifically identified the failure to include information in the Medication Guide as evidence that the defendants had not met their state failure to warn obligations.

I have more, but I want to make sure I'm answering your questions, Your Honor.

THE COURT: Well, you're helping. And I understand that you believe there are criticisms that are not pre-empted that are not among these five. But tell me about your, your view of how you approach applying *Levine* to number two, never tested in the 75 dose.

MR. MOSKOW: Yes, Your Honor. So, actually, I appreciate that.

So if we go to Section 14 of -- it's actually in the original launch label as well. So this is both in 88 and 5881.

In both of those labels you'll see there is language, and I'm -- it's hard to -- I want to make sure you can read it as I'm putting it up on the screen. But you'll see that there's language in "Clinical Studies," Judge, which specifically identifies that an approval is based on the RE-LY study that compared two blinded doses of Pradaxa, 110 milligrams twice daily and 150 milligrams twice daily.

So there is information in the launch label for physicians that indicates that the 75-milligram dose had not been tested.

Now, it is made more clear in the subsequent label which I, I showed you, Exhibit 88, where they specifically identify in Section 12.3 that severe renal impairment was not studied.

But -- actually, I think I missed the screen there. But severe renal impairment was not studied. But there is information here, Judge, where a physician could identify the 75-milligram dose was not tested.

So the FDA has already approved this language being communicated. This is not a question of whether the FDA would approve it. They did. There is no evidence in the record that defendants ever sought to include similar language, plain language in the Medication Guide and that the FDA rejected it.

So what we have here is evidence that the language was

requested. It was included in the physician's label. We have no evidence that it was ever rejected -- requested or rejected from the, the Medication Guide.

And this is a defense. This is not plaintiffs' obligation to disprove. This is defendant's obligation to prove that the matter is pre-empted. And they can't meet their burden based on the, the language of the labels.

As we indicated in our, our opposition papers, Judge, if you look at the five statements that are there -- I just want to be very clear. We were responding to a motion. And that motion attacked these five opinions.

It didn't mention our other labeling criticisms regarding the failure to include a therapeutic range, the failure to identify a test -- Dr. Plunkett talked about the fact that we need to know exactly what excessive dabigatran exposure is and that information isn't in the label.

She talked about the fact that there's a close correlation between the amount of Pradaxa and the bleed risk. That specifically wasn't in the label.

And, Your Honor, I think the best evidence of how important that is was when we heard from Dr. Abdelgaber who testified repeatedly that he was not aware you could get too much Pradaxa based on his understanding of how the drug worked. The company knew you could, but he didn't.

So I think the issue of -- and I could go on, but the

issue of whether these labeling criticisms have been made and whether there's evidence in the record, you know, I'll, I'll leave to my colleagues to, to argue in the next motion.

But what's, what's most important for purposes of this discussion is that the defendants cannot show that with regard to these five items, the FDA would not have approved a request for them to be included in the Medication Guide.

And the reason for that, Your Honor, as identified in our, in our opposition is that all five of these claims were either added to the physician label -- or all five of these warnings were either added to the physician label after the launch label or included in the launch label. And there's no evidence that they were ever sought to be included in the Medication Guide.

That really goes back to I think a fundamental misunderstanding of how the FDA works. You know, FDA knowledge at a point in time is irrelevant if the defendants did not provide all of the analysis that they had of the data.

And what we heard from Michelle Kliewer is that on multiple issues that are germane to these specific warnings and the others that were identified by Dr. Ashhab and, and Dr. Plunkett, those analyses of that data were never provided or were provided at a time after the, the decedent took the drug.

One of -- you know, we saw a transcript reference to one statement that Mr. Childers made about evidence that we were going to show that the family was never warned. And he, he talked about the Medication Guide. And that is evidence of what the family was not told. What's missing is what they were not told.

But he also used this slide, Judge, which was a clear indication that we were making a labeling criticism that this particular drug required -- well, has a therapeutic range and that there is a need to be able to identify it.

And how do we know that? Because the very next slide Mr. Childers showed was that monitoring was an issue here. And he also showed this slide, Judge, that one in five patients are at unnecessary risk because the defendants were not identifying what the therapeutic range was and how to identify people who are getting too little or too much of the drug.

So, you know, to cherry-pick, you know, one statement from a 48-minute opening I think misses the boat and certainly misses what Dr. Plunkett and Dr. Ashhab testified to.

Just looking at some notes that I'm --

THE COURT: Certainly.

(Pause)

MR. MOSKOW: You know, one of, one of the

difficult things about trying a wrongful death case is that you're trying to reconstruct information. And, obviously, with, with Rick and Claudia, we hope we've told that story to the jury.

But the position that the plaintiffs have asserted here, and I believe that a reasonable jury could draw from the evidence that's been produced, is that had, had these warnings been provided, had Mrs. Knight and her family known that, for example, there was no reversal agent when she had actually been administered Vitamin K, the reversal agent for warfarin, she would not have taken the drug.

I think that's a pretty significant issue here, Judge, because if we look at the launch label and we look at Section 5.1 -- this is Exhibit 5881, Page 2, Your Honor. And if we, if we look at Section 5.1, you'll see I've highlighted nothing.

And that's because if we now go to the January, 2012, label, to that same section, 5.1 -- this is on Page 3 of Exhibit 88 -- we now see that the language "a specific reversal agent for dabigatran is not available."

So that's information that was not in the launch label, Your Honor. It's number four on Mr. Childers's chart. And there's no indication that that information has ever been communicated to the Knight family, not from Dr. MacFarland, not from her nurse, not from Dr. Abdelgaber, not from Rick

and Claudia.

The only evidence that we have that demonstrates that there was no effort to communicate that is the fact that it's not in the Medication Guide. So the Medication Guide in this particular case becomes evidence of a failure to warn, not the violation of the duty, but evidence that it had never been communicated.

And what you heard from, from the physicians was that there were times when Mrs. Knight needed to have her anticoagulant reversed and it was.

The last thing, Judge, I just wanted to touch on before I sit down and I may go back to -- would you mind bringing that slide up, please? Thank you.

Your Honor, what's particularly interesting about this chart is that everything ends up pre-empted. There's, there's no way based on this chart to ever update the label.

MR. LEWIS: That's not true. Hold on. It says "claim not pre-empted" right there. Let's get it right here.

MR. MOSKOW: I'm sorry. We have one, one way apparently to get there.

Let's, let's really walk through this, though, Judge. Can the proposed change be made without FDA approval?

So in this particular case what we're saying as it relates to the label is whether they can communicate

specifically to the physician that there's a therapeutic range, there's a value not to exceed, there's a way to identify patients at excessive risk, and that Coreg in particular -- and we, we've made the comparison to Verapamil but specifically identifying Coreg among the other claims that Dr. Plunkett and Dr. Ashhab mentioned.

All of those are based on information that was developed by the company after the launch label either through re-analysis of the RE-LY trial, through post-marketing studies in the population, or through changes in science. It's not a static process.

Did the plaintiff demonstrate there was newly acquired information? Through papers that were published after the date of the drug, the Eikelboom paper from 2011, the Wechsler paper from 2015, the Reilly paper from 2014. We identified that there were changes that became known after the date of approval.

And significantly, Your Honor -- and I have to admit I don't know whether Dr. Ashhab testified to this. I just don't have a specific memory of it. But in his report he specifically stated, "Boehringer Ingelheim --" "had Boehringer Ingelheim instructed Ms. Knight's physicians to measure dabigatran levels and provide guidance on how to measure and interpret her dabigatran plasma concentration, it is more likely than not that they would have found hers

to be elevated and they would have either reduced her dose of Pradaxa further or switched her to another readily available anticoagulant to prevent such a deadly complication."

MR. LEWIS: I've got to -- I mean, I was objected to during my argument. He did not testify to that. And I'll pull the transcript if I have to because that --

THE COURT: Well, I think counsel just acknowledged he wasn't sure what --

MR. LEWIS: He's arguing the evidence.

MR. MOSKOW: But my point, Your Honor, is that the, the citation for that comment was the Reilly Lehr paper. The 2014 re-analysis that the Court has heard testimony went through many iterations that removed from it a clear indication of a therapeutic range, removed from it the idea that patients' outcomes could be improved by testing to see if they were at excessive risk of exposure.

But let's go to the next one.

THE COURT: Well, before you do that, so it would be your view that the things you just listed would fall within the area where Boehringer could have used the CBE process and modified its labels to include those specific warnings.

MR. MOSKOW: That's correct.

THE COURT: And as a result, those aren't

pre-empted.

MR. MOSKOW: That's correct.

THE COURT: Where would you -- how would you apply that same test to these and which are things that are in or not in the label issue?

MR. MOSKOW: So, Your Honor, every one of these items is in the label, is in the physician's label. The, the lack of it being in the consumer label, the Medication Guide is evidence that the defendants never properly warned the Knight family of known risks and hazards of the drug that went directly to their ability to make an informed decision about the risks and benefits.

It's not, it's not de facto. It's not because it's not there, we win. It's evidence that the jury can consider in combination with the fact that, as Dr. Plunkett testified, there was no "dear healthcare professional" letter. There were no, no direct-to-consumer advertising that indicated these changes.

And, you know, what's particularly significant, Your Honor, is that items one, two, three, four were not in the launch label. Those were all added afterwards.

But our point is that because they were added afterwards, there was a potential that they could have been added to the Medication Guide. But it's irrelevant to our claim.

Our claim is the fact that they weren't means that there's no evidence that the Knight family ever received warnings that were germane to their consideration. And the inclusion in the label, the inclusion of these things in the label, particularly after the launch, is evidence that the company identified these as important risks that needed to be taken into account for purposes of a risk-benefit analysis, yet failed to actually communicate them to the people under West Virginia law who were required to get them.

THE COURT: All right.

MR. MOSKOW: I believe -- Your Honor, unless you have more questions, I could probably go on talking for a while, but I think you know the issues and you --

Mr. Childers wanted me to remind the Court and myself, apparently, that our claim starts in November of 2011; that had this information been communicated to Mrs. Knight at that point in time, her family would not have made the decision to put her on the drug. The three of them would not have gone on the drug.

So the fact that there were subsequent failures to warn is significant and we think it shows a reckless disregard for patient safety that would lead a reasonable jury to conclude that punitive damages are warranted.

But the gravamen of the claim is that as of the time

she went on the drug, the defendants knew or should have known each one of theses things and they didn't communicate them to Betty Knight or her family.

THE COURT: All right. Thank you.

All right, Mr. Lewis, I'll give you a few minutes of rebuttal.

MR. LEWIS: Thank you, Your Honor. Just a few things, Your Honor, in response.

We cited the regulation -- we cited the regulation in our papers, but I did want to indicate to the Court that the C.F.R. section that we're relying on is 21 C.F.R. 314.70. And the Medication Guide is called out in there.

And, and the argument that was just made was exactly the argument that we think makes the claim pre-empted. We can't change that label. Remember, we get back to conflict pre-emption.

The question is, are they trying to make us do something under West Virginia tort law that we can't do under federal law. And the answer is "yes." The argument is you should have put all of these things in the physician label in that Medication Guide or otherwise communicated those to the plaintiff directly. And that's the kind of claim that's pre-empted.

Now, I want to address the argument that we should have asked because that's, that's dealt with directly in the

Mensing Supreme Court decision. And that argument was made; you should have asked.

And here's what the Supreme Court says. "The Court rejects the argument that their pre-emption defense fails because they failed to ask the FDA to change the label."

THE COURT: But wasn't it in the context where the generic manufacturer was sued and the claim was the generic manufacturer should have asked the FDA or asked the brand name manufacturer to change it?

MR. LEWIS: Yes. That was the case. But it's exactly the situation that we have here. Here's why.

The Medication Guide is akin to a black box warning or a generic label in the same sense that you can't change it without FDA approval.

There's this other path where you can voluntarily change some things. That's the CBE. But the Medication Guide is just like a generic label. You can't change it unless you first get FDA approval.

And so what they argued in the generic case is just what the plaintiffs are arguing here. You should have asked. And because you didn't ask the FDA, the claim isn't pre-empted.

And the Supreme Court rejected that argument right here. It said that's -- you're not -- the pre-emption defense is still good even if you could have asked and you

didn't ask. The reason why is you're engaging in all kinds of speculation. And this is what the Court says.

It would render the pre-emption defense, conflict pre-emption all but meaningless. It's enough to hold that when a party -- and this isn't limited to generics here. This is a statement by the U.S. Supreme Court.

When a party cannot satisfy its state duties without the federal government's special permission and assistance, which is dependent on the exercise of judgment by that federal agency, that party cannot independently satisfy those state duties.

So this isn't limited to generics. It's any time that you need the FDA approval and the other side is trying to say you should do something else that you don't have FDA approval to do, the claim is pre-empted and you don't have to ask. That's what, that's what the law of the Supreme Court says right there.

And that's why the Medication Guide argument and all of the arguments surrounding the Medication Guide, it should have been in there, we should have said this, we should have said that --

THE COURT: Even if I agree with you, why shouldn't the relief be restricted to instructing the jury clearly that plaintiff is not claiming that the Medication Guide is defective or fails to warn because the Medication

Guide can't be changed without FDA approval?

MR. LEWIS: I would be -- I think that is an appropriate relief here. I really do. I think that this jury is going to be extremely confused if the Court doesn't give that instruction. I mean, at a minimum the Court has to instruct the jury that in my view.

The directed verdict should be granted on that -- however the Court wanted to frame that piece, that has to be the instruction because they're going to be way too confused if we don't instruct them of that.

THE COURT: All right. I know you folks had some discussions about instructions. And yesterday you indicated you've got some more coming. Do you all have an instruction that addresses that?

MR. LEWIS: We'll work on one because I wasn't sure how this was going to play out. But I also want to point out a couple of things about the label challenges if I may.

So part of this may be a dispute about what the relevant label time period is. And the Court may just have to decide that as a matter of law what the relevant -- because it's not really a jury issue. It's, it's --

THE COURT: Why isn't it a jury issue to determine at what point the company should have warned her, or whatever it is the jury ultimately concludes, was the

failure to warn?

MR. LEWIS: Because the, the operative prescription and ingestion of medication that is at issue in this case took place in 2013.

So there was ingestion of medication that allegedly led to an injury that took place in 2013. And, so, the Court for purposes of assessing the pre-emption defense should look at the label as it existed at the time that that allegedly offending prescription and ingestion was made.

In all of the, all of the things that were complained about, including the P-gp inhibitor, the Coreg, Pradaxa, the no reversal agent, those were all from the January, 2012, label. They were, they were already in the label to physicians by the time the allegedly offending prescription and ingestion of medication was made.

I think just a straight up issue that the Court can find for purposes of pre-emption; that that's, that's the label we have to address is that one because we have completely different physicians involved at that time.

I mean, if there was testimony in the case from a doctor that had prescribed the medication for two years and testified that never got a new label, never saw a new label and just kept renewing the -- but that's not the facts here.

The facts are that we have a brand new physician, Stephanie Graham, in 2013 who in the first instance

prescribes Pradaxa that's the allegedly offending prescription and ingestion. And the label that existed at that time was the one that has all of the information.

THE COURT: But under West Virginia law applicable to this case, the duty is on the manufacturer to warn the patient.

MR. LEWIS: And that's where we get into the Medication Guide again because the company doesn't have -- the company has one avenue to communicate with the patient. That's the Medication Guide. And to suggest that any other communication should have taken place would offend federal law.

That's why the only way to pursue the case for the plaintiffs is to somehow use the physician label to argue that it would have changed plaintiff behavior, patient behavior. That's the only way they can pursue this claim just based on the way the federal regulations are written for this particular case.

I want to just point out one other thing. And this just must have been a mistake. But the launch label --

Can we get Exhibit 5881, Section 10? I believe that has -- yeah.

There's no antidote to dabigatran. There was language in the label that there was no reversal agent, no antidote in the launch, and then it got moved to another section in

the later label. I just wanted to clarify that. That's just -- it must have just been an oversight.

In any event, I think that's all I have, Your Honor. But we definitely will craft an instruction on the Medication Guide for the Court's consideration.

THE COURT: All right. I'll just comment. The defendant -- or the plaintiff only made passing reference to the timing of this. Why didn't you file this motion with dispositive motions?

I'm going to tell you for me the biggest problem is that suddenly, less than 24 hours ago, you present me with a pretty nuanced and complicated pre-emption argument. And I went back and looked at the summary judgment motion you filed and there was a three- or four-sentence reference there to pre-emption. But it was in the context of a warning that has never really been at issue and certainly hasn't been presented here. So --

MR. LEWIS: Right. Well, I have two responses to that, Your Honor.

The first response is there's no waiver of a defense. The thing that's going to go up on appeal is whatever the trial record is.

And even in the *Dolin* case you see that what happened was there was a verdict against the defendant. And during the trial, the defendant put in pre-emption evidence that

was eventually relied upon by the Court of Appeals and that's why the reversal took place based on those facts. But they, they only looked at the trial facts.

And, so, as we got into this case and saw what the plaintiff presented, in our view it led to a very strong pre-emption defense that maybe we weren't exactly sure how the plaintiffs were going to present their case on summary judgment.

Now, the other thing is there are a lot of cases out there. Now the *Eliquis* case, the *Utts* case from the Southern District of New York is a motion to dismiss, but there are a lot of other cases where courts are finding factual issues in the context of pre-emption. And we wanted to wait to get all the facts in before we made our defense in this case to be honest.

And I apologize to the Court that we, you know, made a complicated defense during trial, but we're permitted to do that. We don't waive anything by not filing a summary judgment motion or a motion to dismiss on these issues. So I guess that's, that's my point.

The other real point, though, is we've been trying to figure out what their theory is here all along. And I'm not criticizing the plaintiffs, but they've bounced around quite a bit throughout this case.

We didn't hear -- if you watched the depositions of the

physicians, you don't see a lot of testimony about the Medication Guide and what was in it.

Then all of a sudden we get to trial and we see a frontal attack on the Medication Guide, I think perhaps because the law of West Virginia that applies in this case is a little bit different than what we're typically used to as pharma lawyers on both sides with learned intermediary. Perhaps the cases change a little bit.

So I would, I would also suggest that, you know, both sides have made some modifications to the way they present this case given that it's a different dosage than we're used to in some of these cases and also a little bit different law.

But there's no waiver issue because we didn't have to raise it at summary judgment. We can, we can base it on the trial evidence.

Thank you, Your Honor.

THE COURT: All right. Thank you.

All right. Do you want to sur-reply briefly?

MR. MOSKOW: Very briefly, Your Honor. Literally it fit on three post-its.

THE COURT: Go ahead.

MR. MOSKOW: There's a huge difference, as Dr. Plunkett testified to, between warnings and other information in the label.

The inclusion of no reversal agent in the overdose section in the launch label, but then the prominent placement in the risk of bleeding warning in subsequent labels is an incredibly significant change, one that was never communicated by "dear healthcare professional" letter, was never communicated to patients or specifically here Betty Knight and her family.

And I want to make clear, Your Honor, far from only having one avenue to communicate with patients, the defendants in this case -- the defendant in this case has availed itself of at least two other methods, direct-to-consumer advertising on TV and direct-to-consumer advertising in print.

If they wanted to communicate these risks, they had the ability to do so. There is no evidence that that was communicated to Mrs. Knight or her family.

Secondly, Your Honor, you've already ruled on which labels are at issue for the jury as part of the summary judgment and motion *in limine* practice that happened in a timely manner in this court.

And as the -- as Mr. Childers reminded me and I said to the Court, the plaintiffs' claim is that Mrs. Knight would not have ever started on this drug had she been adequately warned. So the label in effect at the time she first started is significant. The label at each time she refilled

her, her prescription was also relevant.

The one thing there's no evidence in this case, though, is this physician who -- I don't even know her name, the physician who put her on it in April of 2013 because that has not come before this jury. That's not an issue for purposes of directed verdict.

What is an issue under *Ilosky* vs. *Michelin* is that it's black letter law in West Virginia that the adequacy of a label is a jury question. It's not a question of law.

And then, finally, Your Honor, the -- the *Johnson* case which is cited in our papers is a direct-to-consumer, not a learned intermediary case. So I wanted to just highlight that for the record.

The final thing I was going to say, Your Honor, by way of sur-reply is that, as the Court pointed out, *Mensing* -- and, and to the extent that the defense relies on *Pliva* were totally different situations.

In those situations under both law and regulation the defendants, who are generic drug manufacturers, had no ability to change their label absent a change in label of the name brand.

That's not the situation we have here. This is the name brand manufacturer. They actually did change their label. And pre-emption is not a valid defense.

Thank you, Your Honor.

THE COURT: All right. Thank you.

Okay. Let's go to motion number two.

MR. HAILEY: Good afternoon, Your Honor.

I want to focus my argument on two issues; first, proximate cause, otherwise known as warnings causation, and then I want to focus on our punitive damages argument.

On warnings causation there are, there are three key arguments I just want to flag for the Court. We briefed these issues. I just want to flag what we think are the most important.

The first is that there has been no evidence in this case that Mrs. Knight ever actually read the Medication Guide at issue here.

I just heard Mr. Moskow say that plaintiffs' claim in this case is that Mrs. Knight would never have started this medicine if she'd been properly warned. And I think that that's the, that's the case that they've put on. Notwithstanding what we've heard today about physician labels, the case has focused on the warnings that were communicated to, to Mrs. Knight.

But there's, there's been no showing of proof by the plaintiffs that Mrs. Knight ever actually read the Medication Guide.

THE COURT: Have you gone back and looked at the opinion I did on summary judgment? I haven't, to be candid

with you, since this came up yesterday.

But I think I addressed this and I think I made findings based upon argument as to what that evidence might be.

Can you point to evidence that I cited as a reason for denying summary judgment on this issue that evaporated at the trial in plaintiffs' case?

MR. HAILEY: Well, sure, Your Honor. I think on, on summary judgment the evidence in the record was the deposition testimony and the briefing. But we just had Mr. Knight and Ms. Stevens testify in court yesterday. And I think that's, that's the evidence that plaintiffs have put forth in this case and that's what we should be focusing on.

THE COURT: Well, I agree. But my point is I think I laid out what I understood the evidence to be and why it was sufficient. Now they've put on their evidence.

What about what they argued have they failed to produce here? That's what I'm really getting at. How has it changed? What's changed from the record I had before me at summary judgment to the actual evidence at trial that makes this now deficient?

MR. HAILEY: Well, let me, let me first state what we didn't hear yesterday when Mr. Knight and Ms. Stevens testified.

They, they never testified that their mother actually

read the Medication Guide. They were never asked, "Did your mother read the Med Guide? Did your mother receive the Med Guide at the pharmacy? Did you ever see a copy of the Med Guide in your mother's possession?" They were never asked any of those questions. They could have been asked those questions to answer this issue.

Going back to summary judgment, the only evidence -- and this was -- we heard a little bit of this yesterday. The, the only evidence that the plaintiffs can point to on whether or not Mrs. Knight actually read a Medication Guide is the testimony from Ms. Stevens.

And first Ms. Stevens testified that Mrs. Knight, quote, kept papers, end quote, from the pharmacy in a drawer in her house. She also said that -- Ms. Stevens when she was shown the Pradaxa Medication Guide on the screen yesterday, she said that that was the kind of paper that her mother would keep in a drawer.

But she never said that that, that she saw the Pradaxa Medication Guide specifically, that she -- she could never give anymore unequivocal testimony that --

THE COURT: Why doesn't that just go to the weight of the evidence and let the jury decide? She testified that it was her practice for her mother to keep the papers she got from the pharmacy. I don't think there's any question in the evidence that would include a label and a Medication

Guide. And I think the -- maybe one of the other doctors or other experts testified that's what goes with a prescription.

So what they got was evidence that it was her practice to keep that type of paperwork. One could infer -- and I think there was at least in Rick Stevens's testimony that he -- or Knight's testimony he knew that she actually read the information about warfarin because she brought up the fact that the, she had a problem with it or an allergic -- something -- there was something like that. I'm going to get this confused.

But, in any event, there was evidence from them that -- from which a jury could infer that she may have read the label and/or the Medication Guide.

MR. HAILEY: So a couple of responses.

THE COURT: Go ahead.

MR. HAILEY: I think from the evidence that's come in the case we, we know that Mrs. Knight was on a whole host of medications. I don't think there's testimony that she kept every paper that she received in connection with her medications; that she kept, may have kept some papers from the pharmacy.

And also the fact that she received papers from the pharmacy and put them a drawer, there's been no evidence, no proof that she ever actually read any of those warnings.

And that's what, that's what is important in this case is whether she read and understood and the warnings were actually communicated to her by reading the Medication Guide. And there's been absolutely no proof on that point.

And plaintiffs could have offered that proof. Mr. Knight and Ms. Stevens were in this courtroom yesterday and they, they --

THE COURT: Well, I agree it's pretty thin and I've been concerned about that from the beginning. What I plan to do is go back and first review the summary judgment discussion of this and then compare that with what I understand the evidence to be.

I know you cite a couple of cases. But in the cases where I've seen where the judge has taken this issue from the jury and decided it as a matter of law were cases where people testified they did not read the papers that came with the prescription.

And we certainly don't -- that's on the other end of the continuum and we certainly don't have evidence like that here. So we're somewhere in between.

MR. HAILEY: Well, unfortunately we don't have testimony from Mrs. Knight in this case. And I, I think the best testimony there is from Mr. Knight and Ms. Stevens is that they don't know. And I think that's, that's a failure of proof on plaintiffs' part because --

THE COURT: Okay.

MR. HAILEY: -- that's one of the elements of their claim is they have to show proximate cause.

THE COURT: All right.

MR. HAILEY: The, the second warnings causation argument that I just want to flag is there also has been no showing that a different warning in this case would have made a difference.

The standard -- this is under *Meade* vs. *Parsley*. The standard is that the plaintiffs must establish that the warnings suggested by the plaintiffs would have caused the patient, Mrs. Knight, to act differently or otherwise change her behavior in a manner which would have avoided her injury.

And, again, I think, I think it will help just to go through the testimony on this point because the plaintiffs submitted a long brief with a long chart sort of summarizing their view of what the, the evidence has been in this case.

But comparing what plaintiffs say in their brief to what is actually in the transcripts and the testimony that's actually come in in this courtroom, it's, it's -- what plaintiffs say is inconsistent with what the jury has heard.

Mr. Knight was asked about the October 17th, 2011, office visit with -- at Dr. MacFarland's office where Pradaxa was first prescribed. He said that he didn't

remember the details of that meeting.

This is in -- and, and we submitted a copy of the, yesterday's transcript this morning and flagged some testimony for the Court.

I think the most important testimony there is Rick saying, "I don't remember the meeting at all." That's at Page 917, lines 7 to 14.

THE COURT: But then didn't he also say that there was -- upon asked specific elements of the warning plaintiffs have advocated that he wasn't told those things?

MR. HAILEY: Well, that's where I wanted to go next.

THE COURT: Okay.

MR. HAILEY: So on that question he was first asked, "If you had known any of these things, would you have requested that your mom be switched from warfarin to Pradaxa?"

And any of those things was focused on those, those five criticisms plaintiffs have made of the Med Guide.

Rick's answer was, "Would I have -- if I had known this? I think it would have been -- it would have played into the decision. I can't say 'yes' or 'no' because I didn't, you know, we didn't have to make that decision."

"I can't say 'yes' or 'no.'" That's definitionally a failure of proof if he can't say "yes" or "no."

Now, plaintiffs' counsel came back and followed up and pressed him about that answer. And ultimately he -- Mr. Knight testified if he had had that information today, it might have changed his decision.

But that's not the issue before the jury. That has nothing to do with the issue here. The question is would that decision have been made in October, 2011, when the prescription was made.

THE COURT: Well, I mean, I don't know that I read quite that much into his statement or answer to if he knew this today. I think a reasonable person when asked this question, he's thinking in terms of, "If you tell me today about this stuff, yes, it would have affected what I would have done before."

I mean, it's -- to me, that really is up to the jury. I tried to listen pretty carefully to his testimony. I certainly agree it wasn't very strong. But he did testify specifically that these were things he didn't know about, and if he had known about them, I think a jury could find that his answer was, yeah, he would have spoken up.

It is pretty clear from the evidence from he and his sister that they were the ones who initiated this whole plan to change to Pradaxa. And I think they each testified that they were pretty involved, especially Rick, with her medications. He's the one who put her pills together for

her, things like that.

So it does seem very reasonable for a jury to conclude that the children played a substantial role, characterize it as significant, substantial, however you want to, but a real role in helping their mother decide what to do.

And in this particular instance, they were the ones who suggested to her and made the arrangements to talk to the doctor about changing to Pradaxa. And they said if they had known these things, they wouldn't have made that suggestion.

MR. HAILEY: Well, I think that, that goes -- that's a good segue to the third point that I wanted to make on warnings causation.

THE COURT: Okay.

MR. HAILEY: And that's what we see as a real gap in the proof the plaintiffs have put on. That's -- there's no, there's no nexus between the warnings criticisms that the plaintiffs are making on the one hand and the actual facts that we heard yesterday of the communications and the information that was communicated in this case. And let me, let me explain what I, what I mean.

Plaintiffs' labeling expert, Dr. Plunkett, when she took the stand she, she criticized the Medication Guide. Plaintiffs' counsel now, you know, say that she was criticizing the Medication Guide and the labeling more broadly.

What we didn't hear from Dr. Plunkett and what we haven't heard until today is any criticisms of TV advertisements or direct-to-consumer advertising regarding Pradaxa.

The, the plaintiffs' case has, has focused on criticisms of the Medication Guide and maybe to some extent the doctor label. But --

THE COURT: I thought Rick testified in particular that he remembered the ad, and maybe it was his sister instead. Somebody testified they remembered the ad. They remembered particularly that it said you don't have to be monitoring this, you can eat all the greens you want, words to that effect, and nothing else about any other aspects of significance in changing to Pradaxa.

MR. HAILEY: Well, that's, that's what I'm sort of getting to. The, the, the expert case that they've put on has been a criticism of the Med Guide and, and possibly the doctor warnings.

Dr. Plunkett didn't, didn't get up and offer any criticisms. She, she could have. She, she purports to have expertise on those areas. She could have offered criticisms about the DTC or the other promotional materials. She didn't.

The first we heard about those TV ads was yesterday. And the reason is because there's no dispute that, that Mr.

Knight and Ms. Stevens, they never saw the Medication Guide. So that's, I think, where the disconnect is, that the warnings that the jury is hearing about, those are in the Medication Guide and the doctor label.

Then we have the testimony about the TV ad. There's no, there's no link there between these warning criticisms that plaintiffs have been making and then the actual communication, the information that came through the TV ad.

We haven't even seen -- other than, other than the very brief testimony about -- I believe it was Ms. Stevens who recalled that the ad she thought said no monitoring and you can have leafy greens. That's all that we've heard.

Plaintiffs have not tried to play the advertisement. They haven't shown any, you know, a script of the advertisement. That information is in the, is in the material that has been produced as part of this litigation. They could have put on evidence of that and -- but they have not. And that's, that's an important gap here because this -- what, what plaintiffs are arguing should have been communicated is in, is in one bucket of information. That's in the Med Guide. But --

THE COURT: Or the label. I mean, it's not just --

MR. HAILEY: Correct.

THE COURT: All right.

MR. HAILEY: But there's no dispute that Mr. Knight and Ms. Stevens never saw the Med Guide, never saw the label. It's not an absence of proof. There's no, there's no question there that they, they didn't see those materials.

All they saw was an advertisement that -- the first the jury's heard about was yesterday and plaintiffs haven't offered anymore information on what supposedly was in that advertisement.

THE COURT: I want to think about this because it does seem -- sometimes I feel like we're chasing our tails on some of these issues.

But plaintiffs have the burden of proof. They have to prove that the warnings were inadequate. They've had one or two people testify about seeing an ad, understanding from that ad only that Pradaxa sounded like a really good choice for their mother because you didn't have to have monitoring and it would ease up her diet.

And then they testified that they met with the nurse practitioner and the doctor and these specific things were never brought to their attention.

So I'm just curious, why would a jury not be able to infer -- you never produced any TV ad where you said, well, yeah, we say all this stuff in the TV ad. So they've said they never got the warning and it's deficient because it

didn't address these things. And they say the source of information is the TV ad. Then why couldn't the jury infer that the TV ad was insufficient to convey these warnings?

MR. HAILEY: Mr. Moskow talked about how the TV ads are subject to a, a regulatory approval scheme just like labeling and the Med Guide. We've all seen the TV ads with all the fair balance, all the --

THE COURT: I'm sure you have.

MR. HAILEY: -- narration. I mean, just of, of pharmaceutical drugs in general, the DTC ads. They, they walk through all the warnings, all the fair balance. We, we haven't heard that.

The evidence that's been put on has been misleading to the jury on -- it's, it's just --

THE COURT: Well, we're probably chasing a loose end we don't need to because I don't understand them to argue that there was a deficiency in the TV ad itself or the TV ad somehow violated some requirement.

MR. HAILEY: Well, if Your Honor doesn't understand there to be a deficiency in the TV ad and that's the one communication, that's the only nexus between the company and Ms. Stevens, Mr. Knight, and Mrs. Knight, then there couldn't be a breach of any duty to warn.

THE COURT: What about when they sit down with the nurse practitioner and discuss the medicine?

MR. HAILEY: Well, that's -- I think then we're getting into the situation of talking about the, the physician warnings that the company provides as part of the doctor label. And that -- again, the case that we've heard over the last week and a half has been about the warnings to the patient. That's, that's the standard that -- that's the standard under West Virginia.

You know, we also, of course, communicate a lot of the important safety and efficacy information to doctors. But that's not what plaintiffs have been arguing and that's -- I don't think we heard anything yesterday from Mr. Knight or Ms. Stevens about information that, you know -- I think the testimony from Mr. Knight was he doesn't even really remember that meeting.

THE COURT: Okay.

MR. HAILEY: I think I can, I can just jump now to punitive damages. I think plaintiffs', plaintiffs' brief that they filed with the chart makes, makes pretty clear that their warranty claims are co-extensive with their failure to warn claims.

They rely -- if you look at the chart, they rely on the same causation element for their warranty claims as they do for their failure to warn. They -- it's either talking about the label or TV ads. Those are the, those are the two communications that -- excuse me -- the Med Guide and the TV

ad. Those are the communications that they're pointing to. So I think we've already covered those in argument.

And just, just very briefly on the punitive damages. When, when Mr. Moskow was, was arguing the pre-emption motion, he walked through a number of areas of, of warnings that were included in the doctor label but not included in the Med Guide.

And, in my view, that sort of encapsulates why this is not a case where a punitive damages claim is appropriate because how can you say that the company is exhibiting reckless indifference or, or malice to patients when we are warning doctors -- we are putting warnings out about this information that plaintiffs are saying that we have not been warning about, and it's just a matter of, well, we're warning the physicians and we're not providing quite enough information directly to the patients?

That to me -- that, that fact that -- we are, we are warning of this information. It's just plaintiffs are arguing about the adequacy of the warning. That should, I think, defeat the punitive damages claim.

And I just want to direct the Court's attention to a case which I believe plaintiffs' counsel mentioned in their pre-emption argument. And that's *Ilosky* vs. *Michelin Tire Corp*. That's a West Virginia Supreme Court case, 307 S.E.2d 603. And I think -- I just wanted to flag very quickly the

language from that case.

"The evidence showed that Michelin had taken steps to warn the public about mixing radial and conventional tires. These efforts included placing warnings and recommendations against such action in literature distributed to consumers and to individual dealers who carried Michelin brand tires. The fact that these warnings may have been inadequate to fully warn of the hazards of such use does not obviate the fact that Michelin made some effort. This case does not involve a situation where the manufacturer or distributor made no effort to warn about the use of the product. Therefore, the facts do not meet the willfulness, wantonness, or malice standard."

And that, I would submit, is this case as well and that's why punitive damages should --

THE COURT: What about the evidence that the plaintiff has put on through these email exchanges and other communications where there's a fairly explicit discussion about the reluctance of the company to increase these warnings to address some of these medical issues because they were afraid that it was going to hurt the marketing of this product as compared to your competitors?

MR. HAILEY: Well, I think we would obviously dispute plaintiffs' characterization of those emails.

THE COURT: Understandably. But if the jury looks

at those and thinks plaintiffs got the right characterization, wouldn't that support punitive damages?

MR. HAILEY: Well, I think -- I mean, most of those emails were relating to a paper, the Reilly paper, the 2014 Reilly paper that was ultimately published. Those emails discuss this question of whether monitoring is appropriate.

That's a, that's a question that has been explored extensively, publicly among regulators, among the scientific community. And that's -- the consensus now is the data does not support monitoring.

So that would be, that would be our response. I think we've already brought that, that evidence in during plaintiffs' case. We are going to continue to develop that record.

But I don't think that -- I don't think the evidence currently supports -- given the warnings, given the fact that even on those monitoring issues there are warnings relative to monitoring relative to the 10th to 90th percentile of plasma concentrations. Those are included in our label.

We proposed the warning to the FDA about an 82nd threshold for the aPTT that would be essentially a monitoring warning. That was rejected by the FDA. I think there's evidence that we have proposed these warnings.

We're, we're now in the world where we're talking about the adequacy of the warnings, not whether we warned at all. And that's the *Ilosky* case and that's --

THE COURT: Well, adequacy in the timing.

MR. HAILEY: Well, we proposed -- prior, prior to approval we proposed a warning about the aPTT test.

THE COURT: Right.

MR. HAILEY: That was, that was before Pradaxa was ever prescribed to a single patient in the U.S. And that was proposed. That was rejected by the FDA.

And even after, even after -- our approval label still included data about plasma concentrations from the RE-LY trial so that physicians could take that information. They could see using those aPTT numbers who's in the top 10 percentile, who's in the bottom 10 percentile.

THE COURT: Well, you know, I do think that if it gets to the jury, it's going to have to be focused and limited and would only be with regard to whether the jury would find that BI used its marketing or financial interest as -- protected its marketing and financial interest at the expense of the adequacy of its warnings.

I think you even had a couple of your people who said the efficacy and safety of the product is the number one consideration. So if there's evidence that decision-makers in the company essentially failed to follow that direction

and decided because of marketing concerns not to make, issue warnings that were adequate for the safety and efficacy of the medication, the jury could find that that's an intentional act and award punitive damages based on that.

I don't see any other area, but I don't understand why you don't think that's at least a jury question.

MR. HAILEY: I mean, I think from the company witnesses -- I think to a person the company witnesses have, have ultimately testified in the deposition videos that it's, it's medicine. It's medical need. It's science that is driving decision-making at the company. And it's, it's not this other suggestion that we've heard.

THE COURT: All right. Thank you.

All right. For the plaintiffs?

MR. CHILDERS: Your Honor, I'm actually not going to handle this. I just wanted to introduce Emily Acosta from my office. She drafted the response, so we thought she would be the best person to handle this.

THE COURT: Straight to the source.

MR. CHILDERS: She hasn't appeared before you before so I wanted to introduce her.

THE COURT: Welcome.

MS. ACOSTA: Thank you.

So I guess as an initial matter I think it's probably helpful to return to what the standard is for a directed

verdict.

Essentially, the plaintiff needs to offer a prima facie case as to each and every element. I think the intention behind doing our response the way we did is that we wanted to provide the Court with a list that is long but not comprehensive of all of the evidence that we think is relevant to establish a prima facie case which, of course, is a relatively low standard. It's not the standard we would have to meet at summary judgment. And it's also not the standard that the jury will be evaluating. It's a remarkably low standard in that regard.

Also, for purposes of granting a directed verdict, the evidence has to point to a single conclusion. I think probably the conversations with Mr. Hailey indicate that that's not possible here. There is at least for every scientific article he can show you, we can show you another that was presented through Dr. Plunkett or some through Dr. Ashhab. I think that in and of itself indicates that a directed verdict as to all of our claims is inappropriate.

I'm certainly happy to address Mr. Hailey's points, but if the Court has any additional questions as to the other ones he raised --

THE COURT: Well, why don't you respond to his arguments first. And then I'd like to sort of quickly walk through the evidence as well. I appreciate the chart you've

given me. I want to make sure that I grasp it and that I understand how it's responding to the defendant's original motion.

MS. ACOSTA: Sure, absolutely.

I think the, probably first way in which the response is responsive is to show that there is at least a scintilla of evidence, which is the standard, relative to each and every claim.

The other thing that's probably important to mention and that I think has been perhaps glossed over is that plaintiffs can rely on direct or circumstantial evidence. This is perhaps a good segue for Mr. Hailey's causation argument.

It is certainly the case that plaintiff has presented direct evidence of the kinds of warnings that were given to Ms. Knight and her family and the kinds of information that were not included in those warnings.

Again, I think it's important to understand the nature of plaintiffs' claims. Certainly we are not claiming that BI made no warnings. Indeed, we could not do that.

But Dr. Plunkett's criticism in sort of broad strokes is that the warning is incomplete. And, so, the information that is not in the warning is remarkably relevant to the kinds of information which is, you know, detailed on this chart as well, but the kinds of information that the Knight

family did not have that would have made a difference, particularly with regard to this decision as to whether or not this was an appropriate medication for Ms. Knight and whether or not it was a medication that she could safely take.

With respect to direct evidence as to causation, I think we have the Medication Guide. Claudia testified that her mother kept Medication Guides. Dr. Plunkett also testified that pharmacies are required to give Medication Guides to patients when they fill prescriptions.

The physician label which, again, is another way of communicating vis-a-vis the doctor to patients, and BI has clearly availed itself of that mechanism. And those warnings to physicians are relevant, particularly to the extent that they do not adhere to these five criticisms as well as many other criticisms that we do have of the label, including the fact that the label doesn't really tell people how to identify folks that are at a risk of being at an excessive level of a dabigatran concentration. And it doesn't give them a mechanism by which to test that reliably.

Dr. Plunkett speaks at length about the aPTT test. And, indeed, that is reflected in several BI documents that that test is sort of a proxy but not a way to really test. And BI knows that there's a way to test using a test like

hemoclot, for example, directly the thing that you're trying to get at rather than indirectly.

So to the extent that information was known and not communicated to the Knight family, that is relevant and important and helps to satisfy our burden as to causation.

The third piece of direct evidence that I would mention is the TV commercial. You know, I, I was listening to Mr. Hailey's argument about what the ad says and what it didn't say. And the truth of the matter is the ad has never been shown.

So there's no evidence to contradict what it is that Ms. Stevens saw out of the ad. And if they wanted to elicit that on cross, I think they could. But now it's, it's sort of too late, I think, to be able to put on that kind of evidence through her as a way of proving the things she knew and didn't know by virtue of seeing that ad.

With respect to circumstantial evidence, I, I think the Court mentioned Ms. Stevens also testified about a time when Ms. Knight, several years before she switched to Pradaxa, had an adverse reaction to a drug.

In connection with having that adverse reaction, she had mentioned to Claudia that she had taken statins. They caused her legs to hurt. And she stopped taking them. I think that's persuasive circumstantial evidence that if Ms. Knight had appreciated the risk that Pradaxa caused to her

and if she had -- that she would have taken a different medicine or would have decided to, you know, refuse a Pradaxa prescription or would have never suggested that she start taking Pradaxa.

So, again, I, I appreciate maybe that it's, it's not an overwhelming amount of evidence, but it's, it's more than a mere scintilla and I think that's sufficient here.

Also, the, you know, the jury is the one that's tasked with deciding whether or not a label is adequate. Adequacy of a label, that's black letter, you know, West Virginia law. And, you know, there's no reason to take the case from the jury simply on that point.

With respect to the warning causation, there -- again, there's no affirmative testimony that Ms. Knight did not meet or did not read the Medication Guide or did not read the labeling. So it's a little unusual that now after the evidence has already come in BI can introduce the absence of evidence as, as a way of defeating plaintiffs' case.

That's -- that, that goes to evaluating the evidence and the weight of the evidence. It does not go to whether or not the evidence is sufficient to begin with. And that's an inappropriate inquiry for purposes of a directed verdict here.

Also, I, I think it's worth noting that Rick Knight's testimony in a way is actually quite helpful to plaintiffs

because he testified that if he had known then what he's known now by virtue of sitting in this trial and hearing all of these different criticisms of the label and all the different deficiencies of the label that he would have made a different decision which is, is sort of part and parcel of our argument.

If the label had contained additional information that would have clearly identified that Pradaxa was not a good medication for Ms. Knight, he would have made a different decision. I, I think the testimony is particularly helpful in that regard.

The -- I have -- much like my colleague, I have other points that are perhaps jogging around, but the other thing that wasn't mentioned is Dr. MacFarland does testify that the impetus for asking for the switch from Coumadin to Pradaxa was, was because they saw an ad.

And, so, while that, that note may not have more information, Dr. MacFarland's testimony does. And that was also presented to the jury.

Also, I, I would sort of note -- I know that Mr. Hailey mentioned with respect to monitoring that this is a question that the company has explored. I -- you know, while I appreciate that there are documents sort of discussing this as a matter of science, BI's exploration on the topic does not, you know, end the inquiry for purposes of this

courtroom or for purposes of the jury. Obviously, if BI could determine all the facts, the case would be relatively straightforward.

And, and there's ample scientific proof both from our specific and our general causation experts to suggest that BI has made no efforts or arguably insufficient efforts to warn of the dangers of excessive dabigatran concentrations. And this kind of transitions maybe into punitive damages.

The important inquiry here is to ask why because if, for example, it was because the company did not appreciate those risks, that would be a far different case.

This is a case where BI not only appreciates the risk, but they intentionally choose not to tell prescribers in the United States, not to tell consumers in the United States because they don't want to lose money. And that is a fraud claim. That is absolutely a fraud claim. And it's the exact same kind of evidence that you can base a punitive damages award on.

And, you know, again, Dr. Plunkett does testify that BI manipulated the science and that their interpretation of the science is perhaps ingenuous. That would also be a basis for, you know, awarding punitive damages and a basis for concluding that the fraud claim can go forward to the jury and that the jury could award damages based on the fraud claim.

Also I, I think it's, it's worth noting with respect to the DTC advertising that Dr. Huh is the first witness that BI put on. And it was a short clip, but within a few minutes in, he admits that part of how he learned about Pradaxa was through commercials.

I, I think it's a little disingenuous to suggest that consumers are the only people that, that watch commercials. Doctors get information from a variety of sources and the label can still be inadequate.

And I, I've got other tiny points, but I'm, I'm happy to answer questions to the extent you have any.

THE COURT: I think you've responded to their arguments. Thank you.

MS. ACOSTA: Thank you, Judge.

THE COURT: Do you want a brief reply and move on to the instructions?

MR. HAILEY: So I just want to quickly respond on some of the causation arguments that plaintiffs' counsel raised.

There, there is still no testimony in this case that Mrs. Knight read the Medication Guide. Your Honor asked when I was up here earlier about what has changed between the summary judgment stage and the testimony yesterday. And I -- my colleague pulled your summary judgment order and I want to just flag -- this is ECF No. 118 and this is Page 32

of the order.

The Court writes, "Mr. Knight confirmed that Ms. Knight read drug labels." And that was -- that's based on Mr. Knight's deposition testimony.

When Mr. Knight took the stand yesterday and testified in this case, he, he didn't offer that testimony. He did not say unequivocally or otherwise that, that his mother read drug labels. We did not hear that testimony from him and that was one of the bases that the Court allowed this claim to survive summary judgment.

I'll go on. The Court concluded that Ms. Knight kept medication labels and that she was known to have read drug labels meets the evidentiary burden for that question to survive summary judgment.

Now, here, again, we have this suggestion that she may have kept some materials from the pharmacy, no testimony that she read any of those materials. And we no longer have this, this statement from summary judgment about Ms. Knight actually -- Mrs. Knight actually reading the drug labels. We did not hear that testimony yesterday.

More broadly, I would invite the Court to, to read the transcripts from Mr. Knight and Ms. Stevens' testimony yesterday. They're -- I think there are a couple of areas like this where plaintiffs' counsel may be overstating exactly what, what the testimony was that came in.

For instance, in plaintiffs' brief at Page 10 it states -- this is on the causation element for the failure to warn claim. Plaintiffs's brief states if Claudia -- and this is purporting to state what Ms. Stevens testified yesterday. "If Claudia had known any of these additional risk factors, Claudia would not have requested her mother switch from warfarin to Pradaxa."

This is the testimony on that point. And if you look at lines 6 to 9 that's not, that's not the testimony that came in. The question here is, "Did you know at the time that a patient on Pradaxa --" I'm sorry. I'm reading the wrong line.

"If you had known any of those things," and again it's talking about these five issues, "would you have asked that your mom switch from Pradaxa to warfarin?"

That's, that's reversed. That's not, not what plaintiffs are saying is the evidence that we heard yesterday.

Ms. Acosta also I think said it wasn't appropriate for us to be raising an absence of proof at this point in the case. But I'd submit that that's exactly what we should be doing at the directed verdict stage.

Plaintiffs have had their shot to put on their evidence. And if they haven't satisfied their claims at this point, that's, that's why a directed verdict is

appropriate.

THE COURT: All right. Go ahead.

MR. CHILDERS: Can I just address that one last point, Judge?

THE COURT: Well, I'll give you a chance in a minute.

MR. CHILDERS: I'm sorry. I thought he was done. I apologize.

MR. HAILEY: Ms. Acosta also mentioned Dr. MacFarland's testimony suggesting that Dr. MacFarland independently testified about Mr. Knight seeing a Pradaxa ad on TV. And that's, that's not the testimony in this case.

It's lines 122 of MacFarland's deposition, Page 122 lines 9 to 15 as you can see. This is plaintiffs' counsel making the representation that, that Rick saw that ad, not any independent testimony by Dr. MacFarland.

And I -- since Ms. Acosta raised the issue of the fraud claim, I just wanted to -- and this may help the parties on figuring out our jury instructions issues.

Fraud requires a, a higher showing. That's clear and convincing evidence. I think as we've already talked about with, with the causation, this is -- if, if you accept that there is -- you know, to the extent that there has been any evidence that Mrs. Knight actually read these warnings, it certainly doesn't reach a clear and convincing standard.

There's certainly not enough evidence here to meet that higher burden required for a fraud claim.

Also, on the, on the warranty claims, the plaintiffs are required to show that an affirmative statement of fact that is, was false or, or inaccurate was actually affirmatively made.

And, again, looking at the evidence in this case, there's no evidence that the, that a Med Guide was ever actually read by the patients or Mr. Knight or Ms. Stevens.

And this, this one suggestion about the DTC ad, that's, that's all there is. There hasn't been any showing that those statements are false or misleading. We don't even know really what the statements were in the ad.

THE COURT: Well, you brought up something that I'm glad you did because I want to ask plaintiffs about that. I think I understand your argument with regard to implied warranty. I want to see what they say about the express warranty.

MR. HAILEY: And then finally just one minor point on Dr. Huh about him mentioning the commercial.

Dr. Huh is -- he's not a prescriber in this case. He doesn't, he doesn't prescribe Pradaxa. He wasn't asked about that. He was -- he performed the surgery. So --

THE COURT: Okay. Thank you.

MR. HAILEY: Thank you.

THE COURT: All right. Mr. Childers, you wanted to respond to one particular point and then I'd like Ms. Acosta to address the warranty claims. I'll give her a chance to reply on that because they didn't mention those in the opening argument.

MR. CHILDERS: I appreciate that, Your Honor.

The transcript there -- first of all, it's not certified because it came from yesterday.

Second of all, I have to believe that the words "from" and "to" were transposed. The question I asked, "Would you have asked her to be switched to Pradaxa from warfarin?" She never was switched from Pradaxa to warfarin. That clearly never happened.

So I'm kind of shocked they would get up and make that argument here as part of their causation. But certainly if we need to listen to the tape or whatever it may be, I know I didn't say that and there's no evidence that she ever moved from Pradaxa to warfarin.

THE COURT: All right. Thank you.

MS. ACOSTA: So I guess to address the other transcript issue, the, the next question and answer that followed in Dr. MacFarland's testimony was whether or not patients often come in after having seen DTC ads and request drugs and she says, yes, that happens.

So, again, I think that there's at least enough for a

jury to reasonably disagree, and clearly Mr. Hailey and I reasonably disagree, as to whether or not that is what the evidence says and whether or not it's sufficient for purposes of a directed verdict here.

I think with respect to the fraud claim -- well, and I guess let me just back up. The *Johnson* case in this regard I think is particularly helpful because it helps us to contextualize and better understand the law in West Virginia.

That case is particularly premised on the idea that pharmaceutical companies have a megaphone through which to communicate with patients. And because of that, they have also a duty, a companion duty to communicate with patients as to the risks they know and the risks that they reasonably should know.

And to the extent that BI failed to do that, I don't think the mechanism really matters because they can either do it vis-a-vis the physician using the physician's label, they can do it using DTC ads, and they can do it during the Medication Guide.

And, yet, despite all of these avenues, they, they didn't adequately communicate a number of, of warnings and a number of sort of risk multipliers that made Pradaxa more dangerous for Ms. Knight and more -- they made it more likely that she would be at an excess dabigatran level and

which, of course, increases bleeding. And there's all sorts of evidence on that point.

With respect to the express warranty, I think, again, the defendant BI in their papers quoted the statute. But what they didn't provide the Court with is case law that interprets that, that statute and tells you exactly what those words and phrases mean. And, and that's in our papers at Page 20 in a footnote.

Essentially, the, the express warranty doesn't -- we don't need to show exclusive reliance or that the reason that Ms. Knight switched from Pradaxa is, is only attributable to the DTC ad. Conveniently, that's kind of what the evidence shows here but that's not our burden and that's not what we're required to do.

And there's, again, the distinction between direct and circumstantial evidence is important and we're allowed to rely on that in, in defeating the directed verdict motion.

THE COURT: Can you particularize for me the statements that you believe are contained within these different sources, the labels, the Medication Guide, and the commercials that were the affirmative statements?

MS. ACOSTA: Sure. So I think in the broad sense it's, it's easier maybe to start with the commercial first because the commercial -- Claudia testified that the commercial communicated to her that the difference, the only

difference between Pradaxa and warfarin was that you didn't have to watch your diet and you didn't have to do monitoring.

If that were an adequate warning, if that were an accurate, correct, factually true statement, it would also have to have included all sorts of information about the particular risk factors that Ms. Knight would have had. It wouldn't be an equally safe alternative to warfarin. It would have had to include more information.

And for that reason, that's why that's West Virginia sort of black letter law that a failure to warn claim is sort of encompassed in a -- or I'm sorry. That's backwards.

An express warranty or an implied warranty claim is sort of encompassed and, and relies on a lot of the same evidence that's used to prove a failure to warn claim because essentially a failure to warn claim is, is premised on the idea that the information was either inaccurate, incomplete or absent.

Obviously, it's not absent but we've proven it's inaccurate and it's incomplete. And that's the information that we need for purposes of statements.

And, again, that information is, is most clearly reiterated in the commercials, but it's also in the Medication Guide and we've pointed out, I think, a number of factors and deficiencies with respect to the Medication

Guide.

This is also true of the label and there are more sophisticated criticisms of the label. But, again, the, the thrust of our case is not that the ad provided no warnings. It's that the warnings weren't complete.

And it's not that the statements were -- and it's rather that the statements were misleading. They were inaccurate. They weren't true. And that's, that's a warranty claim. And that's an implied merchantability claim. And it's also an express warranty claim. BI doesn't have to say this is a warranty in order to create that as a matter of common law in West Virginia.

And, again, in, in our papers we cite the, the, I guess it's *Keefer* (phonetic) vs. *Wyatt* (phonetic) case that talks about the co-extensively of products liability actions and warranty claims.

I don't know if I've glossed over something that --

THE COURT: Thank you. Briefly?

MR. HAILEY: Very briefly, Your Honor.

I think Ms. Acosta's response sort of made clear our view that all of their, all of their claims here are alleging sort of the same thing. And we don't think it's proper to send, send five claims to the jury that are making the same allegation.

This case has been about the Med Guide. It's been a

failure to warn claim and talk about alleged omissions from a label for a Med Guide.

To the extent that plaintiffs are going to now claim that there's, there's misleading or false evidence in the Med Guide, I would say I don't think the evidence supports that.

I would also direct the Court to the *Wyeth* vs. *Levine* case. We cite this quote on Page 3 of our pre-emption motion.

"The FDA will approve an NDA only if the agency finds, among other things, that the proposed label is not false or misleading in any particular."

I think that undermines their, their warranty claim, their fraud claim, and any allegations that we are affirmatively making misstatements.

If it's their claim that there are omissions, then that should go to the failure to warn. But they shouldn't be able to send all these co-extensive claims that are making the same allegations.

THE COURT: All right. Thank you.

Okay. I'm going to take this under advisement.

What's the status of your instruction deliberation?

MR. CHILDERS: We had a productive meeting. We just got red line versions back from the defense. If we could have 20 minutes or so to go through them and see if we

come to anymore agreement before we bring you our --

THE COURT: That would be great. We'll take a 20-minute recess.

MR. CHILDERS: Thank you, Your Honor.

(Recess taken at 3:11 p.m.)

(Back on the record at 4:01 p.m.)

THE COURT: All right. Does someone want to summarize your progress and what remains at issue?

MS. JONES: I'm standing so I guess I'll start, Your Honor.

So, as Mr. Childers mentioned, we had a productive session this morning. We now have a red-line document that we've shared with plaintiffs' counsel, and we're happy to hand a copy up to Your Honor and to your clerk, if that would be helpful. And I think we can walk through the issues that we have, and we can let you know where we have agreement, if that makes sense in terms of the process.

THE COURT: That would be great.

MR. CHILDERS: That sounds good.

THE COURT: All right. Lead the way.

MS. JONES: Sure.

So, Your Honor, basically what we did was took the defendant's proposed set and then made adjustments. And we flagged some places where there are objections and issues, and we integrated some proposals by plaintiffs where we may or may not have agreement.

So I guess we'll just go, starting from instruction No. 1 on page 2, where we're in agreement on that as an appropriate introduction.

THE COURT: Okay.

MS. JONES: Instruction No. 2, we're in agreement on direct and circumstantial evidence.

THE COURT: Okay.

MS. JONES: Instruction No. 3, we're in agreement on the credibility instruction.

THE COURT: All right.

MS. JONES: Instruction No. 4 -- we had a section that included essentially limiting instructions. The first instruction relates to foreign labeling. As the version that you have is edited here to replace the words the 75-milligram dose with Pradaxa, that is agreed upon.

THE COURT: Okay.

MS. JONES: There is -- we've also proposed a limiting instruction with regard to the topic of failure to test. I believe that was an instruction that plaintiffs' counsel wanted to review and confer about further.

MR. CHILDERS: Your Honor, on that particular instruction, plaintiffs would request that the third and the last sentences be struck, and then we would be fine with the remainder of that.

THE COURT: So the sentence starting further?

MR. CHILDERS: Yes, sir.

THE COURT: First tell me, why do you object to the further sentence?

MR. CHILDERS: I don't believe that's an accurate

statement of law, Your Honor. It's failure to warn, and the jury has heard there's been a failure to inform the Knight family that there was no clinical testing. I don't think we can now tell them, because there is no law to support it, that they can't consider that as a failure to warn.

And then the last sentence, the process of clinical testing performed is not considered a risk or danger associated with the use of Pradaxa, there's no legal support for that either.

MS. JONES: Well, Your Honor, as to the first issue, which I guess is the third sentence in that proposed instruction on failure to test, our view is that the Woodcock versus Mylan case, cited on page 7 of the red line, 661 F.Supp.2d 602, which is a case from this district, advises that a failure to warn cause of action covers situations when a product may be safe as designed and manufactured, but which becomes defective because of the failure to warn of dangers which may be present when the product is used in a particular manner.

We don't view that fact of how a medicine was tested to be a danger of the medicine necessarily. We view that to be an appropriate statement of the law as to that third sentence.

As to the remaining two sentences in that instruction, I suppose we could probably agree to cut those out, but we

think that third statement is an accurate statement of the law.

THE COURT: I'm not sure I even understand what the last sentence means.

MS. JONES: Well, I think it feeds into the third sentence, which is this idea that if the obligation is to warn of the dangers of a medicine in a context like this, the testing or lack of testing is not a danger of the medicine.

The danger of the medicine would be bleeding --

THE COURT: Oh, I see.

MS. JONES: -- in the case of a medicine like Pradaxa.

But, as I mentioned, we believe that the third sentence in that instruction is appropriate under the law. If plaintiffs have objection to the fourth and the fifth sentences, we would be fine with cutting those out.

MR. CHILDERS: Your Honor, you may imagine I disagree.

I do believe the fact that there is no clinical data, there is no testing that was done is important information that relates to the risks that a patient is going to undertake by using a medicine that hasn't been tested. That clearly is something that goes directly to the risk-benefit analysis a patient would make as far as whether or not they would be willing to take that.

And, additionally, Your Honor, Dr. Friedman's testimony -- he was the first witness we played. He testified

he couldn't say one way or the other if this medication was safe for severe renal patients, and he works for Boehringer. So clearly that goes to the warnings and risk benefit.

THE COURT: Well, I agree with plaintiff as to the first sentence, the first disputed sentence: Further, BI cannot be liable for failure to provide a warning in the clinical testing of Pradaxa. I think that sentence should stay in.

MR. CHILDERS: Stay in or come out?

THE COURT: Come out.

MR. CHILDERS: Thank you.

THE COURT: I think the last sentence is confusing to even say what you purport to want it in for.

MS. JONES: Well, just -- and I think the last sentence is probably not a sentence that we are -- you know, it's not a hill that we are going to die on necessarily.

THE COURT: Right.

MS. JONES: But I think the concern that we have about the way that the evidence has come in during the trial is there's been a lot of emphasis on testing, whether the company tested. Dr. Plunkett spent a good bit of time criticizing the company for failing to conduct tests.

We don't think there is any question that in West Virginia there is not a standalone failure to test claim. We want to be clear that the obligation of the company is to warn

of the dangers of the medicine, not necessarily to conduct certain testing or even to provide information about what type of testing was done.

So that was the goal and the spirit of this particular instruction. And so I think the fourth sentence, if we are taking out sentence three, becomes more important because we need to be making clear for the jury what exactly they're supposed to be considering with respect to the company's obligation to warn.

MR. CHILDERS: We didn't object to the fourth sentence, Your Honor.

MS. JONES: Oh, okay.

MR. CHILDERS: It was the third and the fifth.

THE COURT: I'm looking at the fifth, the last sentence.

MR. CHILDERS: Sorry, Phyllis.

MS. JONES: No, that's fine. I may have misunderstood.

THE COURT: Okay. So that's what I -- the process of clinical testing performed is not considered a risk or danger associated with the use of Pradaxa.

If what you're saying is that the process of clinical testing --

MS. JONES: I think what we're trying to say is the company doesn't have an obligation necessarily to warn about

every way in which the medicine was tested or not tested.

The obligation under West Virginia law is that you warn about the risks or the dangers of the medicine, which --

THE COURT: I think if you said that, I would be okay with it. So if you want to figure out a substitute sentence --

MS. JONES: Okay.

THE COURT: -- that says that, at least I think that presents a statement that I understand, and we will see if you can craft one that the plaintiffs agree with or not. And if not, we can deal with it later.

So I'm just going to make a note here that the defendant will propose an amended version of that sentence.

MS. JONES: Okay. Thank you, Your Honor.

On page 7, we put this in limiting instructions, although Mr. Childers, I think rightly, pointed out that it's probably not really a limiting instruction. And if the Court was inclined to provide it, we probably want to put it somewhere else.

But it relates to the relevance of physician warnings and the extent to which the jury is permitted, particularly on the record that has come out in this particular trial, that Mrs. Knight relied on her doctors, her children, and she trusted her doctors and relied on their judgment in making decisions about her medical care, that this is an appropriate

instruction to give. Particularly since the physician labeling, based on the discussion that I believe we had with regard to directed verdict, is very much in play in the case.

THE COURT: Okay. So the only disagreement between the parties is where to put this language, not the use of this language?

MS. JONES: I think we have --

MR. CHILDERS: No, Your Honor.

THE COURT: Okay. Sorry.

MS. JONES: Go ahead.

MR. CHILDERS: Your Honor, we would object. That's not -- there's no basis in law for this, first of all.

They can argue to the jury, if they'd like, all of the different ways they believe they provided warnings to Betty Knight and her family, but the law in West Virginia is that the warning goes to the patient. So if you then instruct them that there's law that warnings to the physician somehow is interplayed with that, that is going to confuse the jury because I do believe that is not a correct statement of the law here.

And we would have to list -- if we were going to do this, we would need to list direct-to-consumer advertising, magazine articles, television articles [sic], every other way in which information is provided to patients. This is unnecessary, and I think it's an inaccurate statement of West

Virginia law.

THE COURT: Well --

MS. JONES: Your Honor, just to respond to that.

We're certainly not suggesting anything other than what we all understand to be the case under West Virginia law. We're just -- we think it needs to be clear to the jury that that's something they may consider as they evaluate the adequacy of the warnings to Mrs. Knight.

MR. CHILDERS: And my point on it, Your Honor, is they can argue that all day long. That's how this works. We don't have an instruction that is going to tell them a list of every single piece of evidence they can consider. The evidence is what the evidence is.

And so to point out this one particular thing in a separate instruction I think highlights for the jury a piece of evidence that is just one piece of evidence in a long list of ways that warnings are communicated to patients. And if we were in another state, I wouldn't be making this argument. But here in West Virginia, that's not the duty. The duty is to warn the patient.

THE COURT: Well, all right. I'm going to think about that one before I rule.

MS. JONES: Thank you, Your Honor.

Our proposed instruction No. 5 on expert testimony was agreed upon by the parties, so we have nothing to discuss on

that point.

THE COURT: Okay.

MS. JONES: On proposed instruction No. 6 regarding the necessity of expert testimony, I believe there was only one disagreement with respect to the first sentence of the second paragraph: For example, the only way that plaintiff can prove that Pradaxa's warnings were inadequate is through expert testimony.

MR. CHILDERS: And, Your Honor, we do object to that sentence for basically the same reason we just argued.

This is an unusual state in which warnings have to be given directly to patients. Everybody that sits in this jury box is one of those people. This is not a case where the doctor is the one who gets the warning. And so, in this particular case, I believe it's appropriate for the jury to use their common sense to know if a warning to a patient was adequate or not, and it doesn't have to be established through expert testimony only.

THE COURT: Yeah, I'm troubled with requiring -- focusing the jury on only expert testimony when it's a direct-to-patient warning that's at issue.

MS. JONES: Well, Your Honor, the basis for our proposed instruction was actually from the J.C. by and through Michelle C. versus Pfizer case, which is 240 West Virginia 571. That's from 2018.

Syllabus point No. 7 provides: The determination of whether expert testimony is necessary to sustain the burden of proof in complex cases involving matters of science, medicine, engineering, technology and the like, is made on a case-by-case basis. When the issues involved are beyond the common knowledge and experience of the average jury, expert testimony shall be required.

From our point of view, given the evidence that's been presented, and the way that it's been presented on the warnings specifically by an expert -- Dr. Plunkett was called to talk about the FDA process, how labeling is created, the contents of the label, why some was good, why some was bad.

From our perspective, the fact of her presence in this trial confirms what is represented here, that they need expert testimony to carry their burden on that.

THE COURT: Mr. Childers, why isn't it the case that expert testimony is needed to show the inadequacy of the warning?

MR. CHILDERS: Well, Your Honor, first of all, I want to point out the case that they cite, this is dealing with a general causation opinion. You see they're talking about animal studies, epidemiology, adverse event reports, core data sheets and FDA regulations. What they're talking about there is testimony to establish a -- if I could back up.

In the Zoloft litigation, there was a dispute whether

Zoloft could or could not cause the injury that occurred. We don't have that here. We know that Pradaxa causes bleeding because they tell us it causes bleeding, and so that is not a warning issue. That is a causation issue.

Here -- and it specifically says just above that, it is talking about how language in the label might be interpreted by physicians. That's not at issue in this case.

I don't know when this case was particularly tried, but I do know the law here has changed since the time that we filed this case, and that now there is a learned intermediary defense for cases that are filed. That may have been the case here. I honestly don't know.

But, regardless, this is talking about general causation, which is not at issue. Dr. Plunkett wasn't cross-examined on, hey, can Pradaxa really cause bleeding? That's never been an issue in the case.

THE COURT: I agree, but what about my query?

Don't you have to have expert testimony to identify the adequacy or inadequacy of the warning? Isn't an expert required to assess what is and should be in the warning?

MR. CHILDERS: I think if it was a direct -- excuse me -- if it was a learned intermediary situation where you were giving a warning to a medical professional, then I agree with Your Honor. But here the duty is whether or not they warned the patient. And so our objection is to say that that

can only be established through expert testimony.

I don't have a problem if they want to say that expert testimony should be considered. But when the -- when the duty is to provide a warning directly to the patient, that's common sense. That doesn't need expert testimony for a juror to say, well, if I knew that, I wouldn't take that medicine.

That's what the testimony has been from the plaintiffs. If we knew that, our mom would have never taken the medicine. We don't need expert testimony for that.

MS. JONES: Well --

MR. CHILDERS: And these are -- I'm sorry.

And the issues that we raise, these are facts about the medicine that went into the label afterward.

THE COURT: It seems to me this ought to be something that the parties could resolve. I think you both make good points.

I think you have to have an expert in a warning case like this because I don't think a lay citizen could offer the opinion as to what ought to be in the label. I mean, I think that perhaps a layperson could testify as to what the meaning is conveyed in the label, whether that's enough or not. But I don't think you could have a lay witness come in and say, yeah, you know, they ought to put eight more statements in this label about whatever the subject is, and automatically that goes to the jury, and that's sufficient just because you

don't have to be an expert to establish a failure to warn a patient.

So that is -- it seems to me perhaps the easiest way to address this is to say something to the effect -- I mean, the whole purpose of this is to speak to experts. Surely there is some way of saying that plaintiffs -- the plaintiffs' evidence includes expert testimony that the jury has to evaluate.

I don't think it's wrong to say expert testimony has to be considered, but I guess this goes maybe further than just saying that.

MS. JONES: Well, we're certainly happy to continue to see if we can sort this out.

The one other example that I would just cite on this general idea, Your Honor, is if you take, for example, their blood plasma monitoring claim, the foundation of that inadequacy claim is all that stuff Dr. Plunkett did for the jury on the flip charts and the boards and, you know, the kind of gingerbread man looking drawing. So none of that is something that is accessible to the lay person and absolutely would have required expert testimony to shore up an inadequacy claim on the basis of that type of scientific evidence.

So, from our perspective, that is exactly why this type of instruction is appropriate.

MR. CHILDERS: I don't disagree at all with what she

just said. I believe that -- that you get back into a causation argument. Is that the need to monitor and assess patients? Well, they disagree that that needs to be done. Dr. Plunkett and Dr. Ashhab testified it does need to be done. The warnings that we're talking about, that's information that they agreed is accurate, and it's whether or not it was transmitted to the plaintiffs or not.

But I'm happy to work with them to see if we can craft some new language.

THE COURT: All right. Well, I'll withhold ruling on it --

MS. JONES: That's fine. I mean, I guess just one response on that.

The scientific judgment of whether or not that data is appropriate for a label, that requires more than just a lay person's understanding.

THE COURT: That's what I think, yeah.

MS. JONES: But we will --

MR. CHILDERS: Fair enough, Your Honor.

MS. JONES: But we will talk about it. Okay. We'll confer on that one further, Your Honor.

I think the next item is proposed instruction No. 7 on deposition testimony. We had made some slight changes to the pattern instruction on this issue, which I think were fine with plaintiffs.

THE COURT: Okay.

MR. CHILDERS: I'm sorry. No. 7?

MS. JONES: No. 7.

MR. CHILDERS: Correct.

MS. JONES: Okay. Your Honor, on proposed instruction No. 8 regarding burden of proof, the original -- and this is a little bit of a curiosity at least to our minds.

The pattern instruction as to each of these last three sentences says, if plaintiffs prove their claim by the greater weight of the evidence, then you may find in favor of them. And then it goes on to say that if the plaintiffs did not prove their claims by the greater weight of the evidence, then you may find for BI.

Our view is that the law is if they make their burden, then they must find for them. If they don't make their burden, then they must find for BI.

And, in fact, that would be consistent with what Your Honor instructed in the pre-charge where you said: Burden of proof. This is a civil case. In a civil case, a plaintiff must prove every essential element in connection with each cause of action by a preponderance of the evidence, not beyond a reasonable doubt.

So, you know, our view is that the pattern is just not an accurate statement of what actually is supposed to happen if there is a determination by the jury in either direction

with respect to the balance of the evidence.

THE COURT: So the pattern instruction uses may?

MS. JONES: It does. We propose must.

MR. CHILDERS: That's correct. And we just would request we get the pattern charge, Judge. That's been found to be adequate in this state.

THE COURT: I'll think about it.

If you like, you can just skip over to the ones where there's an issue.

MS. JONES: Sure. Sure.

THE COURT: I don't intend to necessarily get through all of these, but I'd like to identify as many -- that will give me an idea of what remains to be done.

MS. JONES: Sure.

On proposed instruction No. 11, which is on page 15 of the document that we handed up, I think we basically are in agreement. We've made some additions to the language here to change the phrasing that includes just the reference to death to be injuries including her death. By agreement, that's been changed.

The one big picture point that I don't think we have to hash out in great detail now for Your Honor, but we did want to raise, is that our view is it's not appropriate for the jury to be charged on five different variations of the same failure to warn theory. I think the way that the trial

has been -- has been litigated and the way that the evidence has come in is that there is a single universe of evidence. I think Mr. Childers stood up in opening and said this is all about a failure to warn case.

So, from our perspective, charging them on five different variations on what are all failure to warn theories is not appropriate.

THE COURT: Mr. Childers?

MR. CHILDERS: Judge, I think West Virginia law says that's the appropriate way to handle the claims, and we would ask you to follow that.

THE COURT: I think clearly even when they all depend upon the same core facts, there can be different theories. And even though here these theories all seem to rise or fall pretty much on the same core facts, I think plaintiffs are entitled to pursue each claim that they included in their complaint.

Having said that, I really wonder about the wisdom of putting five -- or at least three claims here that are pretty much going to rise or fall on the same evidence. I think it's going to be more difficult for the jury and more instructions and more confusion. But I think plaintiffs have a right to go to the jury on each claim that they presented if the evidence gets them to the jury. And subject to my ruling on the directed verdict, that is where we are.

MS. JONES: Understood, Your Honor.

THE COURT: So --

MR. CHILDERS: And, Your Honor, I just wanted to point out we just noticed on this draft -- and we haven't had a chance to confer with the defendants, but we believe it should be that Pradaxa injured Mrs. Knight and was a cause of her injuries, including death, not was -- and not just caused her injuries and death.

MS. JONES: Andy, where are you looking on the page?

MR. CHILDERS: The first sentence and then the first sentence that is after the broken-out claims.

THE COURT: So you would say what in that phrase?

MR. CHILDERS: So it would say: Plaintiffs' claim that Pradaxa, which was sold by BI, injured Mrs. Knight and was a cause of her injuries, including her death.

I believe that's an appropriate statement of the law.

THE COURT: I think it is, too. And I would assume if it's -- if you've addressed proximate cause somewhere in here, you probably used that same phrase. It doesn't have to be the cause, it has to be a cause.

MS. JONES: Just one moment, Your Honor.

THE COURT: Yes.

(Defense counsel conferring.)

MS. JONES: Okay, Your Honor.

THE COURT: Okay.

MS. JONES: I think those were the only issues on that instruction. Flipping to the next ones where we had disagreement.

On proposed instruction No. 14, this is the outline of the strict liability failure to warn essential factual elements. There was a proposal from plaintiffs for additional language, which has been included in the red line at the bottom. We object to that last paragraph, but we don't have an objection to the statement, Boehringer has a duty to warn patients directly about the risks of Pradaxa, subject to what we have already said about what we think is an appropriate instruction on the fact that the jury may consider warnings to doctors as well.

THE COURT: Go ahead.

MR. CHILDERS: Your Honor, that second paragraph is taken from the Wyeth versus Levine case, which you've heard plenty about already today. I don't think I have to repeat it. But we think it's an important instruction to give, first of all, because it's the law of the United States.

And second of all, because what the jury has heard and will continue to hear is that, hey, the FDA approved this medication and, therefore, it's safe -- and in fact, you gave an instruction in the preliminaries that told the jury that compliance with federal regulations was evidence of -- I can't remember what the word was, but basically saying that what

they had done was okay.

So it's important that the jury know that the law is actually it is the manufacturer's duty, not the FDA's duty, according to the Supreme Court of the United States, to make sure that the label is accurate and the warnings are sufficient.

(Plaintiffs' counsel conferring.)

THE COURT: Do you want to reply?

MS. JONES: Yes. Yes, Your Honor.

THE COURT: Go ahead.

MS. JONES: Your Honor, I guess the one -- the one reaction we had is, one, this seems unnecessary. I mean, they can certainly get up and say this is the evidence that the company owns the label, it's their obligation to manage it throughout the life of the product.

The second point is, you know, there are a lot of statements in different cases that we'd be happy to propose, including from the Wyeth case, that we might put in here. I don't think the idea is that we lard up an already long charge with those types of things. We don't think this necessarily adds to what the jury is already being told about the essential elements.

THE COURT: Well, I think I'm going to include the instruction.

I do have some trouble with the reference there to the

Medication Guide because that sounds like it's awfully close to the claim --

MR. CHILDERS: We don't mind taking that out if the Court --

THE COURT: All right. So it would just be Boehringer is required to -- instead of craft, why don't we say to provide an adequate --

MR. CHILDERS: That's actually the language from Wyeth. But if you want to use different -- they used the word craft, but if you think there might be a better word for this jury --

THE COURT: I think it's clearer just to say to provide an adequate -- I would say to provide adequate warnings for Pradaxa, and leave it at that.

MR. CHILDERS: Yes, sir.

MS. JONES: So just to be clear, Your Honor, it would say: Therefore, Boehringer is required by law to provide an adequate warning label for Pradaxa?

THE COURT: Well, actually to say: Boehringer is required by law to provide adequate warnings for Pradaxa.

MR. CHILDERS: And would the rest of the sentence remain?

THE COURT: Right.

(Defense counsel conferring.)

MS. JONES: I apologize, Your Honor.

THE COURT: That's okay.

(Defense counsel conferring.)

MS. JONES: Your Honor, I think we've made our objection for the record.

To the extent that we're drawing on the Wyeth case, we might have an additional sentence that we think is appropriate given --

THE COURT: Okay.

MS. JONES: -- the fact that this instruction is going to be included.

THE COURT: All right. We'll see.

MS. JONES: And, Your Honor, I apologize for taking us backwards.

But on instruction No. 11, to the extent we're making a change where it says was a cause --

THE COURT: Yes.

MS. JONES: -- would it be appropriate or we think it would be appropriate under West Virginia law to say was a proximate cause.

THE COURT: Do you have a proximate cause instruction somewhere --

MS. JONES: We do.

THE COURT: -- in here?

MR. CHILDERS: Yes, Your Honor.

THE COURT: Then, sure, add proximate there.

MS. JONES: Okay. Okay.

Your Honor, on proposed instruction No. 15, I believe plaintiffs had an objection to this instruction potentially, but they were going to review the underlying Morningstar case.

MR. CHILDERS: Yes.

Your Honor, this instruction deals with state of the art, which we don't believe is at issue with a warnings case. It's more of a design of the product itself.

And in the Morningstar case, although it does say that -- includes the language adequate labels, I think, when it's talking about state of the art, it says that that is to be taken in conjunction with the costs associated therewith. We haven't had any evidence that there was some cost or other prohibitive reason why this label couldn't be changed or whatever instructions and warnings were given couldn't have been given. So I think it's inappropriate, unnecessary and confusing to the jury.

And the other issue is, it's talking about year 2013, and obviously Your Honor has pointed out earlier today that we're talking about a time frame that is broader than that.

MS. JONES: Well, I suspect we could reach agreement on the topic of the time frame, Your Honor. But under the Morningstar case, we think this is an appropriate instruction.

As Mr. Childers mentioned, the Morningstar case specifically refers to having in mind the general state of the

art of the manufacturing process, including design, labels and warnings as it relates to economic costs at the time that the product was made. The fact that there hasn't been evidence entered with respect to costs doesn't mean that that general proposition doesn't apply equally here.

THE COURT: What are you referring to, then, when you say general state of the art? What do we think that is referring to in this case?

MS. JONES: Well, I think in this particular case it refers to the backdrop of what the FDA has typically required. I think it refers to the warfarin label, which is in evidence, and how that label includes certain information, how it's structured, both the doctor label and the Medication Guide. So I think there are some comparators that are relevant for purposes of an instruction like this.

MR. CHILDERS: Your Honor, I would just point out, this came from the pattern charge that only talks about the manufacturing process, and they have struck that language and stuck in there warnings.

The Morningstar case -- although I will confess, I have never heard of state of the art being part of the warnings, and I may just be missing it -- specifically says that the state of the art to be considered is as it relates to economic costs, and that's not at issue in this case. There is no issue that we could not do this because it would be too

costly or too burdensome.

THE COURT: Couldn't change the warning --

MR. CHILDERS: Yes, sir. We're talking about printed labels.

THE COURT: I think this is a confusing instruction, and I think I agree with Mr. Childers. I don't think the context of this discussion in Morningstar was really to address the state of the warnings at the time. I think it's talking about the manufacturing process and design process at the time. And I think the Morningstar case is addressing design defects, not warning defects.

So at this point, I'm going to deny the instruction. If you think a revision of it somehow will meet my objections, you can propose it.

MS. JONES: Okay. Thank you, Your Honor.

I think the next instruction that we had some outstanding issues on was instruction No. 16. And I believe that plaintiffs had some -- I think this tracks the additions we've already made.

Am I right about this, Andy, that we already made to the earlier --

MR. CHILDERS: The addition -- I'm sorry.

MS. JONES: No, no -- the earlier instruction?

MR. CHILDERS: Somewhat. I think that it's just missing the word warn or instruct, the word or, and that would

be consistent with the preliminary instruction that you already gave the jury, Your Honor. You told them warn or instruct, and that's the pattern charge as well.

MS. JONES: And we would just note our objection to the use of the word instruct for purposes of the record, Your Honor.

THE COURT: So let me see if I understand.

On No. 5, do the parties agree that this phrase or instructed on the safe use of Pradaxa -- there's a strikethrough there.

MS. JONES: I apologize. I was not being fully clear.

So at the very top of the page, there's a reference to reasonable care to warn slash instruct, and the word instruct is stricken. The second line.

(Counsel conferring.)

THE COURT: Now I'm afraid I'm more lost than I was.

So we're on 16?

MS. JONES: We're on instruction No. 16, Your Honor.

On the very second line, it says: Plaintiffs claim that BI was negligent by not using reasonable care to warn slash instruct.

BI had proposed to eliminate the word instruct there.

THE COURT: Okay.

MS. JONES: And then in No. 7 --

THE COURT: Right. Okay. So do the parties agree on

the strikethrough at line 5?

MS. JONES: We do not, Your Honor.

THE COURT: That's part of the disagreement?

MS. JONES: That's the disagreement.

THE COURT: Okay.

MR. CHILDERS: I'm sorry I wasn't clear on that, Your Honor.

THE COURT: No, I just didn't understand. It wasn't highlighted.

I think this is really pretty nitpicky for you all to be worried about, to be blunt about it.

This has been discussed primarily as a warning. I don't know that either side used the word instruct with regard to any of the messages to patients or doctors or otherwise, so I am inclined to keep it simple and consistent with the way the case has been presented, and I agree, therefore, with the defendant that we ought just talk about the reasonable care to warn and not include the references to instruct.

MR. CHILDERS: Would that include the fifth sentence as well?

THE COURT: Yes.

MR. CHILDERS: The only other thing would be the addition of the language we talked about in --

THE COURT: I think it's there at the bottom.

MS. JONES: No. We had discussed with respect to

strict liability failure to warn, instruction No. 14, that addition from the Wyeth case. We would just -- we would do the same -- we'd note the same objections to the addition, but I think that that would carry over equally.

MR. CHILDERS: And the Johnson case.

MS. JONES: Oh, right, the one we don't object to.

MR. CHILDERS: Right.

MS. JONES: Yeah.

MR. CHILDERS: I just -- okay.

THE COURT: Okay. So both sides agree to 17.

18, it appears, has a dispute?

MS. JONES: Yes, Your Honor.

So this instruction relates to warning causation. We have made some proposed changes in connection with the case law that we cite at the bottom of the page, which we think is a reasonable encapsulation of West Virginia law on the topic. The principal changes are to make the point that plaintiffs have a burden of proving that a different warning would have made a difference.

And then towards the bottom of the page of that same instruction -- excuse me -- we've proposed that if plaintiffs did not prove that Mrs. Knight read the warnings provided by BI, they cannot prove that different warnings would have caused her to change her behavior. Further, if plaintiffs did not prove that Pradaxa caused Mrs. Knight's death, then you

must find in favor of BI.

So I believe plaintiffs had some objections to some parts of that and perhaps were fine with other parts.

THE COURT: Okay.

MR. CHILDERS: Your Honor, you gave a preliminary instruction on this particular issue at page 4 to 5 of the preliminary instructions. We would ask that you give that again.

And I would also point out that the defendants here again have tried to pigeonhole this into just a wrongful death case, even though there are injury claims as well, and so that would be improper and a deviation from the pattern charge, which I think you read the pattern charge at the beginning of the trial.

THE COURT: All right. I'm going to hold that and look at the preliminary instruction, and we'll talk about it further.

MS. JONES: Okay.

On instruction No. 19, there was an objection by plaintiffs to the second statement, the second element listed under the express warranty instruction. We had proposed that it read that BI made a statement of fact to Mrs. Knight related to Pradaxa.

MR. CHILDERS: Your Honor, this, again, would -- we would just ask that this mirror what you gave in the

preliminary instructions, which said that Boehringer made a statement of fact to Betty Knight that Pradaxa was safe for her. That's what you read to the jury previously, and we would ask that that be what you read to them again.

THE COURT: So I take it what the defense wants is just that BI made a statement of fact to Mrs. Knight related to Pradaxa.

MS. JONES: Yes, Your Honor.

THE COURT: Okay. So if I said in the preliminary that the statement of fact was that the drug was safe for her, why should we not just track that here?

MS. JONES: Well, I think we had an objection to the preliminary instruction as well, Your Honor. So we were just making our objection for the record to the reuse of that --

THE COURT: Okay.

MS. JONES: -- language.

I don't know that there's been any evidence in the record, for what it's worth, that Mrs. Knight ever received any statement of fact that Pradaxa was safe for her. I don't know that anyone has testified to that.

THE COURT: Well, I think there's a lot of dispute about whether she read or saw a label or the Medication Guide or anything else. But if that goes to the jury, then it seems to me the statement that they should focus on that is the source of the express warranty is Pradaxa is safe for you,

Mrs. Knight.

MS. JONES: There is not any evidence to suggest that there was any such representation made to Mrs. Knight. That's the challenge that we have with this particular --

THE COURT: Well, is that --

MS. JONES: -- instruction.

THE COURT: -- because there is a question about whether she read anything?

MS. JONES: Well, I think there's a question of whether she read anything. I don't think there's any question that she never saw any television advertisement at all.

THE COURT: Right.

MS. JONES: And so there was no representation made through that channel.

THE COURT: Well, maybe this will help me grasp some of this for other reasons.

So if there was evidence here that Ms. Knight read the label -- forget the Medication Guide, she read the label -- would you agree that plaintiffs could make a claim that there is an express warranty, and the statement upon which that express warranty can be based is in the label to the effect this Pradaxa is safe for you?

MS. JONES: If there was evidence that Mrs. Knight had seen labeling that said Pradaxa is safe for you, Mrs. Knight, then I think we would not object to that. But there is no

evidence at all in the record that there was any such representation to Mrs. Knight. That is the challenge that we have.

The hypothetical that you're posing --

THE COURT: Well, maybe it's just my inadequate analysis of this, but to me we are sort of meshing two parts of this.

So, first, clearly there is a dispute about whether she looked at or knew anything. Set that aside.

If a patient had the label and read it, would the patient -- if Mrs. Knight had the label and read it, would she not have a claim for express warranty based upon the statement in the label that Pradaxa is safe for you, Ms. Knight?

MS. JONES: No, because that's not in the label.

The label -- the labeling for patients says this is a medicine that could cause you to bleed so seriously that it could cause you to die, and then it lists risk factors for that. It says don't stop the medicine without talking to your doctor first because it could increase your stroke risk.

There is no labeling for Pradaxa -- I don't think the FDA would permit there to be labeling for any prescription medicine that says this medicine is safe for you, person X, Y or Z. That has just not been a representation that there's been any evidence that Mrs. Knight ever received.

That's the challenge --

THE COURT: Well, this is getting -- we are struggling to get through these instructions, but this is something that has troubled me that we didn't really hear much about a few minutes ago when we were arguing these motions.

And I know in your chart you provide a general reference to the express warranties as being statements in various documents, but I don't know what specific statements those were. And typically in an express warranty case, you've got a document, you know, the car brochure or the warranty document from the product, that says a statement in and of itself, and that statement becomes the express warranty. And so I've been troubled by not understanding clearly what express warranty plaintiffs have asserted.

MR. CHILDERS: I'll try to address that, Your Honor.

As you point out, when she got the label -- which, as we know, when you get prescriptions, you get --

THE COURT: Right.

MR. CHILDERS: -- the label and the Med Guide.

The testimony was that she kept the papers that the pharmacist gave her, and we think that she read them.

THE COURT: Right.

MR. CHILDERS: The label that she got with her first prescription said, if you have severe renal impairment, you can take the 75-milligram dose.

THE COURT: Okay. So --

MR. CHILDERS: It didn't say you can't take it, Mrs. Knight, because you're taking a P-gp inhibitor. It did not say that. So that is the representation, that is one of the representations we think, ah, that was made that was inaccurate.

MS. JONES: And putting aside, Your Honor, just our general concerns about the warranty claim that have been addressed in our directed verdict motion, that is why we proposed as to element three that it just say that Pradaxa -- excuse me -- that BI made -- as to element two, that BI made a statement of fact to Mrs. Knight related to Pradaxa, because we've got this situation where we know she wasn't told this medicine is safe for you.

THE COURT: I agree with you. Given the clarification that plaintiffs provide about the express warranties and the source, I don't think that it is appropriate to just simply say the statement of fact that Pradaxa was safe for her standing alone.

So I agree --

MR. CHILDERS: Understood, Your Honor.

THE COURT: I'm going to use the defense version.

MR. CHILDERS: Yes, sir.

THE COURT: Okay.

MS. JONES: On instruction No. 20, which is implied warranty of merchantability, there was disagreement as to

element three, Pradaxa was not fit for the ordinary purposes for which it is used.

There is -- I believe in the pre-charge that Your Honor gave, there was a more robust statement of that element that included a reference to and/or it did not confirm -- conform to the promises or affirmations of fact made in the label or Medication Guide.

We spent a fair bit of time talking about this because what was charged in the pre-charge is not actually what is in the model, but the model then references a statute that includes this additional language. Our view is that this additional language is really going to an express or affirmative representation by the company, and so that really is captured by the express warranty claim and isn't appropriate in an implied warranty of merchantability instruction.

THE COURT: So defendant's position is the instruction that you highlighted in red with the strikethrough is the version you would prefer?

MS. JONES: Yes, Your Honor. And I believe that is the version that is -- I think that's the pattern instruction, if I'm recalling correctly.

MR. CHILDERS: If I may, Your Honor.

The pattern instruction allows for the very specific language you included. The instruction -- and, I'm sorry, I

don't have it right here in front of me -- refers to several things that you can say after such goods are used and/or, one of which is any of the things listed in a specific statute. This language is directly out of that statute, and I believe that's why Your Honor gave that to the jury before.

So it's not accurate to say it's not in the pattern charge. The pattern charge just references the statute instead of typing it all out.

THE COURT: I think I did look at this for the preliminary. I think I'm going to stick with the preliminary instruction version.

MS. JONES: Your Honor, I think the next issue was with respect to proposed instruction No. 22.

(Defense counsel conferring.)

MS. JONES: So I think just to present this as one issue, Your Honor, there are kind of related proposed instructions from both sides. I think we both have objections to our respective instructions.

One is No. 22, which is our proposal on compliance with safety standards, which I believe was in the pre-charge. And then on page 43, we've included a proposal from plaintiffs on -- what I think was described in their proposal is presumption per se -- I think in their proposal it said something other than negligence per se, but this is the language on page 43.

And the discussion that we've been having is the extent to which compliance or noncompliance by the company should be relevant for purposes of the jury's determination.

THE COURT: So plaintiffs are offering a negligence per se instruction.

MR. CHILDERS: What we had proposed, Your Honor, is that we would try to combine some of this language together in one instruction. And what plaintiffs would propose is that the first sentence from -- it's not called negligence per se in the pattern charge, but I certainly can see why it is construed that way.

That if you -- after the sentence that was added to the pattern charge in the preliminary instruction, which was, Compliance with appropriate regulations is competent evidence that BI exercised due care in marketing Pradaxa, we would request that the next -- that another sentence be added that says -- right out of this pattern charge, which I think is 427. It says: "If you find that Boehringer violated one or more state or federal laws or regulations relating to Pradaxa, then the evidence of such violations raises a presumption of negligence.

Because the sentence that was added previously is basically the mirror image of that.

MS. JONES: And we have an objection to that proposed instruction, Your Honor, for two reasons.

One is, to the extent that it really is tracking a negligence per se theory -- and I hate to bring up preemption again -- it implicates a whole different type of preemption, known as Buckman preemption, which is to say there is not a standalone cause of action for violations of the Federal Drug and Cosmetics Act.

The second concern that we have about this instruction is that there has not been any evidence that I can recall or any testimony that Boehringer somehow violated a state or federal law or regulation relating to Pradaxa. So --

THE COURT: Let me stop you there.

What is your evidence of a violation of a federal law or regulation?

MR. CHILDERS: Dr. Plunkett, Your Honor, testified to specific federal CFRs that require warnings to be made that weren't made. But -- and I understand your concern.

Our issue is if we're going to say compliance with regulations is competent evidence, then the jury needs to know if they violated it, which Dr. Plunkett testified they did, well, that's also evidence of a presumption of negligence. So the other proposal I have is to take it out entirely.

THE COURT: Why don't we just add the mirror image of that last sentence and say: Failure to comply with federal regulations is competent evidence that BI failed to exercise due care?

MS. JONES: Well --

MR. CHILDERS: I'm fine with that, Your Honor. I'm sorry

MS. JONES: No problem.

We would still object to that, Your Honor, because we don't -- I don't believe there's been any -- I don't believe Dr. Plunkett ever said BI violated this regulation or this law.

THE COURT: You know, it didn't catch my attention in that way, but I'm going to add the sentence that I just spoke of, the mirror image of failure or a violation of a regulation. But I'm going to go back and look at my notes and perhaps her testimony and see how she brought out a violation of a regulation and what it was specifically before I think it's appropriate to give this.

MR. CHILDERS: Your Honor, I would point out, if in fact you decide that whatever her testimony was didn't get there, they haven't put on any evidence of compliance with federal regulations. And we know they only have two experts coming, neither one of which is an FDA expert, to say we did comply.

THE COURT: Well, you know, there is ample evidence from your witness that there are many statutes and regulations pertaining to the approval of a drug which they complied with. I think they are entitled -- it is uncontroverted evidence

that Pradaxa was an approved drug. I'm not sure the extent to which any of this is really at issue of anything, but there is evidence of compliance with the federal regulatory program. And it seems to me, even in this context, they're entitled to argue we complied with the regulations, we complied with the statute. This is a newly approved drug. We went through that process, we submitted all of the things, and we got that approval.

MR. CHILDERS: Understood.

THE COURT: All right. So I'm going to add that mirror sentence and then look more closely at the evidence concerning violation of the regulation.

MR. MOSKOW: Your Honor, with Court's indulgence, may I have permission to leave? I have a flight home tonight out of Charleston, and I'm not arguing right now, but I didn't want to leave without your permission.

(Off-the-record discussion.)

THE COURT: Go ahead.

MR. MOSKOW: Thank you very much, Your Honor.

MR. CHILDERS: Thank you, Your Honor.

MS. JONES: Your Honor, I think the next issue was with respect to the instructions on punitive damages. We had proposed -- and this is in the bolded text, some additions to the instruction at instruction No. 24, which we believe are supported by the cases and authority that we cite.

THE COURT: All right. I'll just take those under advisement.

And let me say with all of these, my plan would be to the extent to which I've made decisions on some of these things, Blake will have those reflected in a draft. Some of these things obviously I haven't decided today. We will have a chance on the record again to go through a final version of these things before I decide everything and then give the charge.

MS. JONES: We appreciate it, Your Honor.

THE COURT: Blake is leaving, too. He's driving to Richmond this evening, so I'm going to let him go.

MS. JONES: Okay. Thanks, Blake.

THE COURT: And if you just want to call my attention -- the punitive damage instructions --

MS. JONES: Yes, I think through 27 are all punitive things. I'm just looking to see if we have any other hotly disputed issues.

THE COURT: Is there a dispute about a learned treatise?

MR. CHILDERS: No, sir.

MS. JONES: No, Your Honor. That was just an addition that we made, so that is agreed upon.

THE COURT: Okay.

MS. JONES: We did include a proximate cause

instruction that had been proposed by plaintiffs. I think this was largely the model. We had suggested that the reference to or only cause on the second to last line of that instruction was not necessary given what the cases say. I think saying the sole proximate cause adequately covers what the law is in West Virginia. But otherwise, we didn't have a disagreement with that instruction.

THE COURT: All right. I'll take a look at that.

MS. JONES: And then I think everything is -- I don't want to speak too soon, but I think everything else is agreed upon other than on page 44.

Plaintiffs have proposed a so-called concurrent negligence instruction, which we object to because we don't think there has been any evidence or will be any evidence that there was negligence by another nonparty or, you know, party who might somehow be involved in the case.

THE COURT: What do plaintiffs base this instruction on, what evidence?

MR. CHILDERS: Your Honor, there has been suggestion that Ms. Knight's doctors knew about these risks. You heard today that there was a doctor that prescribed her Pradaxa in 2013 who was a new doctor.

Telling the jury that, that may lead them to think that a doctor who is a nonparty to this case is also at fault. And this covers that particular scenario should the jury --

I'll be shocked if it's not argued to them that the doctor was warned and should have known about this. So that covers that issue.

MS. JONES: We certainly intend to argue that her doctors were warned. We do not intend to argue that any of her doctors were negligent. So this instruction, from our point of view, is inappropriate because it specifically refers to possible negligent acts by nonparties or other parties.

THE COURT: So if they agree that there is no evidence that any doctor was negligent in their care and treatment of Ms. Knight, why would you need this?

MR. CHILDERS: I wouldn't if the jury is specifically told that nobody in this case is blaming the doctor.

They're going to -- they're going to suggest it without saying it, Your Honor, is what I'm concerned about. They may not get up and say they were negligent, but they're going to get up and say the doctor knew about all of these risks, and the doctor put her on that medicine. If you're a juror sitting on the jury, that may lead you to believe, well, they're saying it's the doctor's fault, so let's blame the doctor instead of the pharmaceutical company.

If they're willing to stipulate, and we can read a stipulation to the jury that says no party is blaming any doctor for the injuries that occurred to Ms. Knight, I'm fine with that. But I don't believe that they would be willing to

do that.

MS. JONES: Well, I don't think a stipulation is necessary, Your Honor. And I certainly have no intention of saying to the jury that we think that her doctors were somehow negligent in prescribing her the medicine. We think they exercised appropriate clinical judgment based on her medical care, which I think has been the evidence so far and will be the evidence next week. So we view this instruction as being inappropriate.

THE COURT: Well, I want to think about this. I think I see plaintiffs' point.

They may be concerned that the jury -- even if you don't argue it that way, if the jury believes that these warnings are inadequate, that doctor shouldn't have prescribed this for her in April of 2013 and that, therefore, that doctor was negligent, and that's the cause of her taking Pradaxa and somehow alleviates the fault of Pradaxa -- BI, even if they would otherwise find that there were inadequate warnings.

I'll think about that. I think I'm inclined to agree with plaintiff, but I'll give some thought to it.

MS. JONES: Okay.

MR. CHILDERS: Your Honor, I just wanted to point out on the punitive damages charge, we submitted a pattern charge. I don't think that is included in here, but that was our proposal and not the extra charges.

THE COURT: Okay.

MR. CHILDERS: Thank you, Your Honor.

THE COURT: All right. Thank you all for sticking around.

MS. JONES: The one other thing, Your Honor, is that we have conferred also about a verdict form.

THE COURT: Okay. Great.

MS. JONES: They've marked up our version. I'm not sure if it makes sense to march through it right now, but we have discussed that and are in a position whenever the Court is inclined.

THE COURT: Well, I'm glad that you mentioned that.

So at this point, you don't have an agreed-upon verdict form --

MS. JONES: No, Your Honor.

THE COURT: -- but you are still working toward it?

MS. JONES: Yes.

THE COURT: Okay. What I'd like you to do, then, is continue working on it. Bring me up to date on this on Monday morning. If you have not resolved it by a reasonable time Monday morning, like by lunch or at lunch, then I am probably going to require each side to submit proposed versions, and we will see what is at issue.

Have you given any further thought to some type of summary of evidence that you would want to give to the jury?

MR. CHILDERS: Yes, Your Honor. We've been working on that and plan to provide it to the defendants tomorrow morning as you instructed.

THE COURT: Okay. So what I'd like to do, and I may have said this, but I want to know before the end of business tomorrow if you have an agreement and, if you don't, what is agreed, what is disagreed. So if you would file something that reflects that so that I could have it to be looking over over the weekend.

My plan would be -- we're back here at 9:00 on Monday morning. My plan would be to take that up immediately and resolve it, and then bring the jury in and get started.

You're still in good shape with your two witnesses, I take it?

MS. JONES: We are, Your Honor.

THE COURT: All right. Then as far as I'm concerned, we can adjourn until 9:00 on Monday.

MS. JONES: And, Your Honor, just for record purposes, on the jury instructions, do we need to be submitting something to the docket to reflect the parties' respective positions on these things? Obviously this will all be in the transcript, but what would you like us to do?

THE COURT: Here's my suggestion. Part of that depends upon how extensive the disagreement is. You know, obviously you want the record to be clear and as clean as

possible.

I'm happy -- and at this point, from what I've heard, I believe it's the case that you can probably do all of this in a conference, in a hearing where you can simply state these things and not have to file separate documents or supporting documents.

You've each submitted --

MS. JONES: Yes.

THE COURT: -- proposed instructions.

MS. JONES: We've submitted proposed instructions I think on both sides.

We've had some additions --

THE COURT: All right.

MS. JONES: -- based on the evidence.

THE COURT: What I've read here and you've told me about that is in dispute I think can be easily handled on the record orally --

MS. JONES: Okay.

THE COURT: -- as opposed to requiring further documents.

And I don't see a need for you to submit further documents to document -- to put everything on the record and preserve your objections.

MS. JONES: Would you have any -- it would be -- for belt and suspender purposes, would you have any objection to

us just putting on the docket what we had proposed so that we have that on the docket?

THE COURT: When you say what you had proposed, what do you mean?

MS. JONES: It would be essentially what we started with this morning.

THE COURT: I guess I don't mind.

MS. JONES: Okay.

THE COURT: You know, what I am wary of is throwing in a document that entails all of the objections -- or all of the instructions as originally proposed, and then finding out that you are trying to preserve an objection to something that you didn't really raise in these discussions --

MS. JONES: Yes.

THE COURT: -- or with me.

And I don't want to have to be looking over my shoulder to make sure --

MS. JONES: Oh, understood.

THE COURT: -- you know.

MS. JONES: Understood.

THE COURT: I know what's at issue, and I've ruled on what's at issue. That neither side is holding something back, so to speak, just to point to later and say these instructions were offered and rejected.

MS. JONES: That was not our intention at all, Your

Honor.

THE COURT: Okay. So if you feel there is some need to submit some written document, certainly feel free to.

MS. JONES: Okay. Thank you, Your Honor.

THE COURT: All right. Anything else?

MR. CHILDERS: Thank you, Your Honor. Have a good weekend.

THE COURT: You, too. See you Monday.

MS. JONES: Thank you.

THE COURT SECURITY OFFICER: All rise. This court stands in recess.

(Proceedings were adjourned at 5:07 p.m.)

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CERTIFICATION:

We, Kathy L. Swinhart, CSR, and Lisa A. Cook, RPR-RMR-CRR-FCRR, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter as reported on October 11, 2018.

October 11, 2018
DATE

/s/ Kathy L. Swinhart
KATHY L. SWINHART, CSR

/s/ Lisa A. Cook
LISA A. COOK, RPR-RMR-CRR-FCRR